United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508W)
EPA738-R-98-013
December 1998

Reregistration Eligibility Decision (RED)

Bromoxynil

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case 2070 which includes the active ingredients bromoxynil phenol and bromoxynil octanoate. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 23, 1998, contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It also includes requirements for additional data (generic) on the active ingredient to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the receipt of this letter. The second set of required responses is due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that the Food Quality Protection Act of 1996 (FQPA) became effective on August 3, 1996, amending portions of both pesticide law (FIFRA) and the food and drug law (FFDCA). This RED takes into account, to the extent currently possible, the new safety standard set by FQPA for establishing and reassessing tolerances. However, it should be noted that in continuing to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA. Rather, these early determinations will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Karen Jones (703) 308-8047. Address any questions on required generic data to the Special Review and Reregistration Division representative, Linda Werrell (703) 308-8033.

Sincerely,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must

comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

Bromoxynil

LIST B

CASE 2070

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REREGISTRATION ELIGIBILITY DECISION TEAM
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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MAI	Multiple Active Ingredient
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake

GLOSSARY OF TERMS AND ABBREVIATIONS

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	Pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Database
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 © of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
μg/L	Micrograms per liter
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The U. S. Environmental Protection Agency has completed its reregistration eligibility decision for the pesticide bromoxynil, which includes the active ingredients bromoxynil phenol and bromoxynil octanoate. The decision includes a comprehensive reassessment of the required target data and the use patterns of currently registered products. Bromoxynil is a herbicide used mainly on field corn, wheat and grain crops to control a variety of grasses and broadleaf weeds. The Agency has concluded that no uses, as prescribed in this document, will cause unreasonable risks to humans or the environment and therefore, all products are eligible for reregistration. Due to deficiencies in the database, two studies and surface water monitoring are required to confirm the Agency's risk assessment conclusions.

Background

Usage

Bromoxynil is a selective contact foliage applied herbicide used to control variety of grasses broadleaf weeds. Bromoxynil inhibits photosynthetic electron transport and also uncouples oxidative phosphorylation in mitochondria, thereby stopping energy production and negatively affecting plant respiration. Agricultural crop use sites include: food crops (e.g., garlic/onions); food and feed crops (e.g., mint, flax, spearmint, peppermint, barley, oats, rye, triticale, wheat, sorghum, cotton, and field, sweet, and pop corn); and feed crops (e.g., fodder/hay, grass, millet (proso), alfalfa, sudangrass). Non-food uses include: fallow/idleland; outdoor industrial areas; nonagricultural uncultivated areas/soils; ornamental herbaceous plants; commercial/industrial lawns; ornamental (non-residential) lawns and turf; golf course turf; and sod farms. Bromoxynil is formulated as an emulsifiable concentrate, soluble concentrate, and a gel formulation (in water soluble packages). The application rates for crop uses range from 0.25 lb ai/acre to 0.5 lb ai/acre. There are no residential uses for this herbicide.

Human Health Risk

Bromoxynil phenol has been classified as a Group C, possible human carcinogen. Rapid conversion of the ester forms of the chemical (heptanoate and octanoate) permit the risk assessment to be based on exposure to the phenol. The Reference Dose (RfD) for bromoxynil phenol is 0.015 mg/kg/day based on the threshold NOEL/LOEL of 1.5 mg/kg/day in a 12 month-chronic oral toxicity study in dogs. Chronic dietary risk is estimated to occupy less than one percent (1%) of the chronic RfD. The aggregate dietary risk of cancer to the general population from residues in food and water, associated with long-term exposure to bromoxynil was estimated to be 1.7×10^{-6}. The estimated aggregate acute dietary risk, calculated as Margins of Exposure (MOE), all exceed 10,000. Therefore, significant concerns related with acute dietary exposure are not predicted.

The Agency has determined the aggregate risk from bromoxynil meets the certainty of no harm standard. EPA believes that the bromoxynil risk is "negligible". Regarding the aggregate

carcinogenic risk, the Agency does not apply the negligible risk standard as a bright line test because of the lack of precision in quantitative cancer risk assessment. There are a significant number of uncertainties in both the toxicological data used to derive the cancer potency of a substance and in the data used to measure and calculate exposure.

In accordance with the Food Quality Protection Act of 1996, the Agency uses a weight-of-evidence approach to determine whether to retain, reduce, or remove the 10X safety factor required for possible enhanced sensitivity to infants and children. The database for the developmental toxicity of bromoxynil is robust. Developmental effects (supernumerary ribs being the most sensitive indicator) have been observed in developmental and reproductive studies. The Agency concluded that reliable data support using a 100-fold uncertainty factor to assess bromoxynil dietary risk for all populations with the exception of females 13+. Upon review of the extensive developmental toxicological database for this chemical, a concern for *in utero* developmental effects was noted. In order to provide a sufficient margin of safety for the developing fetus, the 10-fold safety factor for enhanced sensitivity to infants and children was retained for females 13+ thus requiring a 1000-fold uncertainty factor for this population subgroup. All MOEs calculated exceeded 10,000 and, therefore, developmental effects to any sub-population are not predicted.

Occupational Handlers and Workers

EPA has established a short- and intermediate-term dermal NOEL for bromoxynil based on developmental effects and has also classified bromoxynil as a Group C quantifiable carcinogen. The handler dermal risk assessment based on the Pesticide Handler's Exposure Database (PHED) data for mixers/loaders/applicators indicates that short- and intermediate-term dermal risks and cancer risks are acceptable (i.e., greater than 100) if such handlers wear chemical-resistant gloves in addition to baseline attire (long-sleeve shirt, long pants, shoes, and socks) while performing mixing and loading tasks and baseline attire while performing applicator tasks. For all tasks, other than mixing and loading, the risks are acceptable for handlers with baseline attire. The cancer risk for the non-commercial handlers (grower) is 2×10^{-6} or lower for all scenarios with baseline attire, except that mixers and loaders must also wear chemical-resistant gloves. The cancer risk for commercial handlers is 1.9×10^{-5} or lower for all scenarios with baseline attire, except that mixers and loaders must also wear chemical-resistant gloves. The highest cancer risk estimated from these particular scenarios was 1.9×10^{-5} (commercial mixer/loaders for aerial applications and sprinkler irrigation). However, these mixer/loader risk estimates do not account for the potential exposure reduction from the use of "wide-mouth" containers (designed to reduce spillage) for mixer/loaders. At the present time the PHED database does not allow the Agency to quantify this risk mitigation measure, however the use of the "wide-mouth" containers would likely reduce the reported risk further. In addition to provide an additional margin of safety, EPA is requiring mixers and loaders to wear a chemical-resistant apron. Although EPA has no data to specifically assess the exposure reduction to mixers/loaders afforded by a chemical-resistant apron, the Agency is persuaded that the exposure reduction would be significant. Available data indicate that the preponderance of non-hand exposure to mixers/loaders is to the front torso.

Environmental Fate

Bromoxynil octanoate was found to be chemically and physically similar to bromoxynil heptanoate. Both esters rapidly degrade to bromoxynil *per se*. Bromoxynil octanoate is mobile and non-persistent. It dissipates in the environment by abiotic hydrolysis, photolytic degradation, and microbially-mediated metabolism in both the aerobic and anaerobic environments. Bromoxynil octanoate readily hydrolyzes to bromoxynil phenol and then further degrades to CO_2. The hydrolysis half-life for degradation of bromoxynil octanoate ranges from 1 day up to 34 days. Degradation is increased by exposure to sunlight and aerobic and anaerobic degradative processes. In two terrestrial field dissipation studies, the observed half-life of bromoxynil octanoate was approximately 14 days in California and 1 day in North Carolina.

Based on the available data, the Agency concludes that the potential for ground water contamination from bromoxynil octanoate is low; it does not exhibit the mobility or persistence characteristics of pesticides that are normally found in ground water. Environmental fate studies indicate that bromoxynil (phenol and octanoate) should not persist in surface waters. The aerobic aquatic metabolism study shows rapid degradation with a half-life of <12 hours.

Environmental Risk

The overall risk to birds (and to insects) exposed to bromoxynil octanoate is expected to be low. For mammals the calculated risk ranges from medium to high, based on known developmental effects. However, exposure levels high enough to cause chronic developmental effects are believed to be unlikely to occur. The acute risk to both freshwater and estuarine fish is expected to be low; chronic risk is expected to be minimal. The overall acute risk to freshwater invertebrates is expected to be medium. The overall risk to both endangered and non-endangered terrestrial and semi-aquatic plants is expected to be medium. And finally, the risk to aquatic vascular plants is uncertain at this time due to a lack of data, while risk to nonvascular plants is expected to be minimal. Additional testing for aquatic vascular plants is required.

The Agency is requiring additional, confirmatory data be submitted. These data include the following: aquatic plant toxicity; and chronic estuarine/marine fish and invertebrates testing. Additionally, this reregistration eligibility decision document reiterates the requirement, Federal Register May 13, 1998, for the submission of an acceptable surface water monitoring program.

Before reregistering the products containing bromoxynil, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C.136 *et seq.* The FQPA amendments went into effect immediately. As a result, EPA is embarking on an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process will include a more in depth analysis of the new safety standard and how it should be applied to both food and non-food pesticide applications. The FQPA did not, however, amend any of the existing reregistration deadlines in section 4 of FIFRA. The Agency, will therefore, continue its ongoing reregistration program while it continues to determine how best to implement FQPA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of bromoxynil. The document consists of six sections. Section I is the introduction. Section II describes bromoxynil, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for bromoxynil. Section V discusses the reregistration requirements for bromoxynil. Finally, Section VI contains the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredients are covered by this Reregistration Eligibility Decision:

- **Common Name:** Bromoxynil phenol
  Bromoxynil octanoate
- **Chemical Name:** [3,5-dibromo-4-hydroxybenzonitrile]
- **Chemical Family:** Benzonitrile
- **CAS Registry Number:** Phenol (1689-84-5)
  Octanoate (1689-99-2)
- **OPP Chemical Code:** Phenol (035301)
  Octanoate (035302)
- **Empirical Formula:** Phenol ($C_7H_3Br_2NO$)
  Octanoate ($C_{15}H_{17}Br_2NO_2$)
- **Trade and Other Names:** Buctril
- **Basic Manufacturer:** Rhone-Poulenc

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of these uses of bromoxynil is in Appendix A.

Type of Pesticide: Postemergence herbicide

Use Sites: TERRESTRIAL FOOD CROP: Grain Crops (triticale), Root Crop Vegetables (garlic, onion)

TERRESTRIAL FOOD+FEED CROP:
Beverage Crops (mint), Crops Grown for Oil (flax) Fiber Crops (Flax), Flavoring and Spice Crops (peppermint, spearmint), Grain Crops (barley, corn field, oats, rye, sorghum, triticale, wheat), Groups of Agricultural Crops Which Cross Established Crop Groupings (cotton), Specialized Field Crops (corn, pop; corn, sweet)

TERRESTRIAL FEED CROP: Forage Grasses (grass, forage/fodder/hay, millet (proso), sorghum, sudangrass), Forage Legumes and Other Nongrass Forage Crops (alfalfa), Groups of Agricultural Crops Which Cross Established Crop Groupings (grasses grown for seed)

TERRESTRIAL NON-FOOD CROP: Agricultural Uncultivated Areas (agricultural fallow/idleland), Groups of Agricultural Crops Which Cross Established Crop Groupings (grasses grown for seed), Nonagricultural Uncultivated Areas (industrial areas (outdoor), nonagricultural uncultivated areas/soils), Ornamental Herbaceous Plants, Ornamental Lawns and Turf (commercial/industrial lawns, golf course turf, ornamental lawns and turf, ornamental sod farm (turf))

Target Pests: Annual Sowthistle, Black Nightshade, Blue Mustard, Broadleaf Weeds, Buffalobur, Canada Thistle, Coast Fiddleneck, Common Cocklebur, Common Groundsel, Common Lambsquarters, Common Ragweed, Common Tarweed, Corn Chamomile, Corn Gromwell, Cow Cockle, Eastern Black Nightshade, Fiddleneck Field, Pennycress, Giant Ragweed, Green Smartweed, Hairy Nightshade, Hemp Sesbania, Henbit, Ivyleaf, Morningglory, Jimsonweed, Knawel, Kochia, Ladysthumb, London Rocket, Mayweed, Pennsylvania Smartweed, Pepperweed, Prostrate Knotweed, Prostrate Spurge, Redroot Pigweed, Russian Thistle, Shepherdspurse, Silverleaf, Nightshade, Spiny Pigweed, Spurweed, Sunflower, Tall Morningglory, Tall Waterhemp, Tartary Buckwheat, Tumble Mustard, Velvetleaf, Venice Mallow, Wild Buckwheat, Wild Mustard, Wild Radish, Yellow Woodsorrel

Formulation Types Registered:

Technical	
Crystalline/Solid	87.30 to 95.00%
Liquid	87.30%
End Use Product	
Emulsifiable Concentrate	15.74 to 33.40%
Liquid	15.74 to 33.40%

Method of Application:

Equipment - Aircraft; Boom sprayer; Center pivot irrigation; Ground; Hand move irrigation; Moving wheel irrigation; Solid set irrigation; Spray sprinkler irrigation

Method- Band treatment; Broadcast; Chemigation; Directed spray; Ground spray; Low volume spray (concentrate); Spray

Timing - Cutting; Dormant; Established plantings; Postemergence; Prebloom; Preemergence; Preplant; Seedling stage; When needed

C. Estimated Usage of Pesticide

This section summarizes the best usage estimates available for the pesticide uses of bromoxynil. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability that result from using data from various information sources.

Summary of Quantitative Usage Estimates for Bromoxynil

An estimated 2.5 to 3.0 million pounds a.i. of bromoxynil are applied annually in the U.S., with usage appearing to be quite variable year to year. Most of this usage (91%) is allocated to three crops: field corn (57%), wheat (26%) and barley (8%). The remaining usage is spread among other grain crops, alfalfa, mint, onions and some minor sites. Crops with the highest percentages of acreage treated are garlic (81%), mint (55%), onions (36%) and flax (13%).

D. Data Requirements

Data required for the reregistration of bromoxynil are outlined in 40 CFR 158.150 through 158.740 for those uses supported by the registrant. There have been five (5) data call-ins (DCI) for this chemical. The first issued on March 28, 1983, required chronic feeding, oncogenicity and teratogenicity studies in one species. The second was issued May 3, 1984 for environmental fate data, including hydrolysis, photodegredation, mobility and field dissipation. The third DCI was issued in June of 1987 to investigate the possibility of polyhaloginated dibenzo-p-dioxins and dibenzofurans (PCDDs and PCDFs) in technical bromoxynil and bromoxynil octanoate. The fourth DCI was issued on August 9, 1988, and required dermal teratology studies in the rat. Finally, in 1991, a DCI was issued for bromoxynil requiring product chemistry data, fish and invertebrate studies and various crop studies. Appendix B includes all data requirements identified by the Agency which are required to support reregistration of currently registered uses.

E. Regulatory History

Bromoxynil was first registered in the United States in 1965 for use as a herbicide to control grassy and broadleaf weeds on wheat and barley. In 1972, tolerances were established for field and fodder crops, meat, and meat byproducts of cattle, goats, hogs, horses and sheep. Throughout the 1980's, a series of additional tolerances were established

for a variety of vegetable, field and fodder crops. Five DCIs were issued over the course of the late 1980s and early 1990s (see above for further details). Regarding dioxin, it was determined by the Agency that the data submitted in response to the 1987 dioxin DCI indicated that PCDDs and PCDFs are not present in the bromoxynil products at levels above the Agency-specified limits of quantitation (LOQs). The Agency has determined that analysis for PCDDs and PCDFs is not required for bromoxynil octanoate produced by the UK manufacturing process. The data received from the 1991 DCI are discussed in the toxicity assessment of this report and are considered in this reregistration decision.

When the reregistration case for bromoxynil was opened, case 2070, bromoxynil phenol, butyrate, heptanoate and octanoate were all incorporated. Subsequently, bromoxynil butyrate registrations were voluntarily canceled by the registrant in 1989 due to concerns related to developmental toxicity. Therefore, bromoxynil butyrate is not included as a part of this reregistration decision. At that time, the Agency also had concerns for potential risks to workers mixing, loading, and/or applying bromoxynil products. To reduce these exposures, the registrant undertook several actions. These included label amendments, development of a new jug (to prevent splashing) and the supply of gloves included in product packaging.

Further changes to the reregistration case came when the registrant decided not to support the heptanoate. However, in 1993, the registrant applied for a new heptanoate registration, which was granted. Since only those pesticides registered prior to 1984 are subject to reregistration, the bromoxynil heptanoate is not considered a reregistration chemical and is not specifically incorporated for this reregistration action. However, there are two products which include both the heptanoate and the octanoate forms of bromoxynil. For human health, all risk values are based on exposure to the phenol (for the two labels that contain both the octanoate and heptanoate, both esters were converted to the phenol and the exposure calculation made). All esters of the chemical are considered to be toxicologically similar to the phenol and, in fact, rapid conversion of the esters to the phenol occurs in the environment. The exposure estimates, therefore, incorporate exposure to the octanoate and the heptanoate included in the two combined labels. The percent crop treated used in the dietary exposure considers all esters of bromoxynil.

In May 1995 (60 FR 27414), the Agency established a time-limited tolerance under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), for residues of bromoxynil on cottonseed. This tolerance expired on April 1, 1997. On May 13, 1998, the Agency issued a tolerance for cotton use. In that Notice, the maximum allowable cotton acreage that can be treated with bromoxynil was increased from 400,000 acres (3% of cotton acreage) to 1.3 million acres (10% of cotton acreage). This document incorporates the information published in the May 13, 1998 Federal Register Notice.

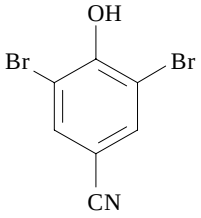
III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

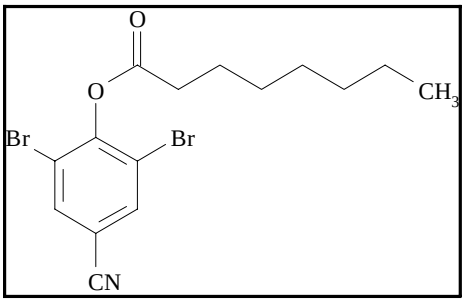
Description of Chemical

Bromoxynil [3,5-dibromo-4-hydroxybenzonitrile] is a selective herbicide which is registered for application as the octanoic or heptanoic acid esters for postemergence control of broadleaf weeds in various crops. There are no active products or registered uses for bromoxynil butyrate (Shaughnessy No. 035303).

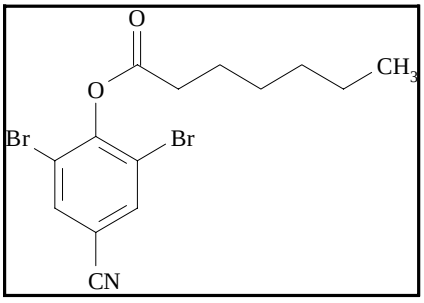
Bromoxynil Phenol
Empirical Formula: $C_7H_3Br_2NO$
Molecular Weight: 276.9
CAS Registry No.: 1689-84-5
Shaughnessy No.: 035301



Bromoxynil octanoate
Empirical Formula: $C_{15}H_{17}Br_2NO_2$
Molecular Weight: 403.0
CAS Registry No.: 1689-99-2
Shaughnessy No.: 035302



Bromoxynil heptanoate
Empirical Formula: $C_{14}H_{15}Br_2NO_2$
Molecular Weight: 389.0
CAS Registry No.: 56634-95-8
Shaughnessy No.: 128920



Identification of Active Ingredient

Bromoxynil is a white to slightly yellow crystalline solid with a melting point of approximately 190 C. Bromoxynil is slightly soluble in water at 211 ppm and in hexane at 178 ppm, and is soluble in 1-octanol (4.97 g/100 L) and methanol (8.51 g/100 mL) at 25 C.

Bromoxynil octanoate and bromoxynil heptanoate are brown crystalline solids with melting points of approximately 44 C. The esters are virtually insoluble in water. Bromoxynil octanoate is soluble in acetone or ethanol (10 g/100 mL), benzene or xylene (70 g/100 mL), chloroform or dichloromethane (80 g/100 mL), and cyclohexanone (55 g/100 mL). Bromoxynil heptanoate is soluble in 1-octanol (33.8 g/100 mL), methanol (52.4 g/100 mL), hexane (77.5 g/100 mL), dichloromethane (111.1 g/100 mL), acetone (106.4 g/100 mL), and ethyl acetate (102.7 g/100 mL). The octanoic and heptanoic acid esters are readily hydrolyzed to bromoxynil under alkaline conditions.

Manufacturing-Use Products

The registered bromoxynil and bromoxynil ester MPs are presented below in Table 1.

Table 1: Technical Registrations for Bromoxynil

Formulation	EPA Reg. No.	Registrant	Comments
Bromoxynil (035301)			
94% T	264-229	Rhone-Poulenc AG Company	TGAI produced by Rhone-Poulenc in the United States.
95% T	264-473		
94% T	33688-8	CFPI Agro	Repackaged from a registered product.
Bromoxynil octanoate (035302)			
95% T	264-442	Rhone-Poulenc AG Company	Produced by the UK manufacturing process.
87.3% T	264-395		
87.3% FI	33688-9	CFPI Agro	Repackaged from a registered product.

B. Human Health Assessment

1. Toxicology Assessment

The hazard assessment addresses issues and data related to bromoxynil phenol and its octanoic acid ester, bromoxynil octanoate, both of which are currently registered with EPA and have been supported for reregistration. Technically, the term "bromoxynil phenol" is a misnomer, the phenolic form of bromoxynil being known more properly simply as "bromoxynil". Nevertheless, the term "bromoxynil phenol" will be used to eliminate possible confusion and to clearly distinguish the phenolic form of the compound from all other forms of the compound. The toxicology data in support of this reregistration case are complete and adequate.

a. Acute Toxicity

The acute toxicity test results and toxicity categories for bromoxynil phenol and bromoxynil octanoate are presented in the following tables.

Table 2a. Acute Toxicity Results for Bromoxynil Phenol

Study	Result	Category
Acute Oral LD_{50} (rat)[1,a]	81 mg/kg (M) 93 mg/kg (F)	II
Acute Dermal LD_{50} (rabbit)[2,a]	>2000 mg/kg (M and F)[b]	III
Acute Inhalation LC_{50} (rat)[3,a]	0.269 mg/L (M) 0.150 mg/L (F)	II
Eye Irritation (rabbit)[4,a]	corneal opacity, iritis, conjunctival irritation	II
Dermal Irritation (rabbit)[5,a]	no irritation	IV
Skin Sensitization (guinea pig)[6,a]	negative	N/A

[1-6] MRIDs 00124758, 00124758, 43014701, 00124758, 00124758 and 42718701, respectively; [a] Test material was technical grade bromoxynil phenol; [b] Abraded skin; N/A = not applicable

Table 2b. Acute Toxicity Results for Bromoxynil Octanoate

Study	Result	Category
Acute Oral LD_{50} (rat)[1,a]	400 mg/kg (M) 238 mg/kg (F)	II
Acute Dermal LD_{50} (rabbit)[2,a]	> 2000 mg/kg (M)[b] 1310 mg/kg (F)[c]	II
Acute Inhalation LC_{50} (rat)[3,a]	0.81 mg/L (M) 0.72 mg/L (F)	III
Eye Irritation (rabbit)[4,a]	corneal opacity, conjunctival irritation	III
Dermal Irritation (rabbit)[5,a]	slight erythema	IV
Skin Sensitization (guinea pig)[6,a]	positive (modified draize test)	N/A

[1-6] MRIDs 00124112, 00124112, 42167101, 00124112, 00124112 and 41879801, respectively; [a] Test material was technical grade bromoxynil octanoate; [b] Abraded skin; [c] Intact skin; N/A = not applicable

b. Subchronic Toxicity

Table 3 summarizes the available subchronic toxicity information. The subchronic studies are described in detail following the table.

Table 3: Subchronic Toxicity Studies

MRID# (Species)	Doses Tested (mg/kg/day)	Systemic Toxicity (mg/kg/day)
Bromoxynil Phenol - Oral		
41469101 (Rat)	0, 28, 58, 168 (♂) 0, 35, 76, 250 (♀)	NOEL (♂) = 28 (♀) ≺ 35 (not established) LOEL (♂) = 58 based on ↑ ALT, ↑ AST, ↑ Alkaline Phosphatase (♀) = 35 based on ↓ body weight gain
42553401 (Mouse)	0, 1.3, 3.9, 13, 39, 130, 390 (♂, ♀)	NOEL (♂) = 3.9 (♀) = 13 LOEL (♂) = 13 based on ↑ liver weights, hepatocellular hypertrophy (♀) = 39 based on ↑ liver weights, hepatocellular hypertrophy, degeneration and vacuolation
43166701 (Dog)	0, 1, 5, 8, 12, 16, 20, 30, 40, 50 (♂, ♀)	NOEL (♂) ≺ 1 (not established) (♀) = 1 LOEL (♂) = 1 based on ↓ body weight gain (♀) = 5 based on ↓ body weight gain, panting, liquid feces
Bromoxynil Phenol - Dermal		
42272301 (Rabbit)	0, 30, 300, 1000 (♂, ♀)	NOEL (♂, ♀) = 1000 LOEL (♂, ♀) ≻ 1000 (not established)
Bromoxynil Octanoate - Oral		
42411901 (Rat)	0, 11, 45, 91 (♂) 0, 13, 55, 111 (♀)	NOEL (♂) = 45 (♀) = 13 LOEL (♂) = 91 based on ↓ body weight gain, ↓ serum total protein, ↓ globulins, ↑ degeneration/necrosis of cardiac myofibers (♀) = 55 based on ↓ body weight gain, ↑ liver weights
42869701, 43700201 (Dog)	0, 0.43, 1.43, 7.14 (♂, ♀)	NOEL (♂, ♀) = 0.43 LOEL (♂, ♀) = 1.43 based on ↓ body weight gain
00061179 (Dog)	0, 1, 5, 25 (♂, ♀)	NOEL (♂, ♀) ≺ 5 LOEL (♂, ♀) = 5 based on occasional panting
Bromoxynil Octanoate - Dermal		
42346201 (Rabbit)	0, 30, 300, 1000 (♂, ♀)	NOEL (♂, ♀) = 1000 LOEL (♂, ♀) ≻ 1000 (not established)

Bromoxynil Phenol

In a 13-week subchronic feeding study, technical grade bromoxynil phenol was administered in the diet to groups of 15 male and 15 female Sprague Dawley rats at dose levels of 0 (control), 400, 755 or 1456 ppm (equivalent to 0, 28, 58 or 168 mg/kg/day in males and 0, 35, 76 or 250 mg/kg/day in females). Decreased body weight gain (22%), increased alanine aminotransferase (ALT), increased aspartate aminotransferase (AST), and increased alkaline phosphatase were observed in males at 755 ppm. At 1456 ppm, signs of severe toxicity and excessive mortality (10/15 died) were also observed in males. Treatment-related effects were recorded in females at all dose levels. These effects were decreased body weight gain at 400 ppm (19%) and at 755 ppm (34%), increased alkaline phosphatase

at 755 and 1456 ppm, and signs of severe toxicity and excessive mortality (15/15 died) at 1456 ppm. For male rats, the NOEL is 400 ppm (28 mg/kg/day) and the LOEL is 755 ppm (58 mg/kg/day), based on decreased body weight gain, increased ALT, increased AST and increased alkaline phosphatase. For female rats, no NOEL was determined in this study (<400 ppm; <35 mg/kg/day). The LOEL is 400 ppm (35 mg/kg/day), based on decreased body weight gain. This study is of limited usefulness because a NOEL was not determined for females, excessive mortality occurred in males and females at the highest dose level tested, and an insufficient number of tissues was microscopically examined. (MRID 41469101)

In a 12-week range-finding study, technical grade bromoxynil phenol was administered in the diet to groups of 10 male and 10 female CD-1 mice at dose levels of 0 (control), 10, 30, 100, 300, 1000 or 3000 ppm (equivalent to 0, 1.3, 3.9, 13, 39, 130 or 390 mg/kg/day). Increased liver weights and hepatocellular (HC) hypertrophy were observed in males at 100 ppm and higher. Degeneration and vacuolization were also observed in the hepatocytes of males at 300 ppm and higher and decreased body weight gain and additional pathological effects in the liver were observed at 1000 ppm and higher. At the highest dose level tested (3000 ppm), all male mice died during the first week of testing. For female mice, increased liver weights, HC hypertrophy, HC degeneration and HC vacuolization were observed at 300 ppm and higher. At dose levels of 1000 and 3000 ppm, effects for females were the same as for males. For male mice, the NOEL is 30 ppm (3.9 mg/kg/day) and the LOEL is 100 ppm (13 mg/kg/day), based on increased liver weights and HC hypertrophy. For female mice, the NOEL is 100 ppm (13 mg/kg/day) and the LOEL is 300 ppm (39 mg/kg/day), based on increased liver weights, HC hypertrophy, HC degeneration and HC vacuolization. This study was a range-finding study. Ophthalmologic, hematologic, clinical chemistry and urinalyses examinations were not conducted. In addition, a complete histopathologic examination was not performed. (MRID 42553401)

In a 13-week range-finding study, technical grade bromoxynil phenol was administered orally in gelatin capsules to groups of 2 male and 2 female beagle dogs at dose levels of 0 (control), 1, 5, 8, 12, 16, 20, 30, 40 or 50 mg/kg/day. Treatment related decreased body weight gain was observed in males at all dose levels tested. At 5 mg/kg/day, occasional panting and liquid feces were also noted and at 8 and 12 mg/kg/day, frequent panting, occasional salivation, unsteady gait, decreased erythrocyte count, decreased hemoglobin, decreased packed cell volume, and increased urea nitrogen were observed. Dose levels of 16 mg/kg/day and higher were clearly excessive and caused mortality and/or signs of severe toxicity. Decreased body weight gain, occasional panting and liquid feces were observed in females at 5 mg/kg/day. At 8 mg/kg/day and higher, effects in females were the same as in males. For males, no NOEL was determined in this study (<1 mg/kg/day). The LOEL is 1 mg/kg/day for males, based on decreased body weight gain. For females, the NOEL is 1 mg/kg/day and the LOEL is 5 mg/kg/day, based on decreased body weight gain, panting and liquid feces. This study was a range-finding study. Only 2 dogs/sex/dose level were used and an insufficient number of tissues was microscopically examined in the control group and at dose levels of 12 mg/kg/day and lower. (MRID 43166701)

In a 21-day subchronic dermal study, technical grade bromoxynil phenol was applied to the shaved dorsal skin of groups of 5 male and 5 female New Zealand white rabbits at dose levels of 0 (deionized water control), 30, 300 or 1000 mg/kg/day for 6 hours/day, 5 days/week, for 3 weeks (24-25 days). Treatment with bromoxynil phenol did not produce any observable dermal or systemic toxicity. The NOEL for dermal irritation and systemic toxicity is 1000 mg/kg/day, the limit dose for a 21-day study. (MRID 42272301)

Bromoxynil Octanoate

In a 13-week subchronic feeding study, technical grade bromoxynil octanoate was administered in the diet to groups of 20-30 male and 20-30 female Sprague Dawley rats at dose levels of 0 (control), 150, 600 or 1100 ppm (equivalent to 0, 11, 45 or 91 mg/kg/day in males and 0, 13, 55 or 111 mg/kg/day in females). An additional group of 30 male and 30 female rats was started at a dose level of 2100 ppm, but was sacrificed during the first week of the study due to high mortality and signs of severe toxicity. No treatment related signs of toxicity were observed in males at 150 or 600 ppm. At 1100 ppm, the following effects were observed in males: decreased body weight gain, decreased serum total protein, decreased globulins, possibly increased thymic lymphocyte necrosis, and increased degeneration/necrosis of cardiac myofibers. No treatment-related effects were observed in females at 150 ppm. At 600 ppm, decreased body weight gain and increased liver weights were observed in females. At 1100 ppm, the following additional effects were also noted in females: decreased serum total protein, decreased globulins, possibly increased thymic lymphocyte necrosis, and increased degeneration/necrosis of cardiac myofibers. For male rats, the NOEL is 600 ppm (45 mg/kg/day) and the LOEL is 1100 ppm (91 mg/kg/day), based on decreased body weight gain, decreased serum total protein, decreased globulins and increased degeneration/necrosis of cardiac myofibers. For female rats, the NOEL is 150 ppm (13 mg/kg/day) and the LOEL is 600 ppm (55 mg/kg/day), based on decreased body weight gain and increased liver weights. (MRID 42411901)

In a 13-week subchronic oral study, technical grade bromoxynil octanoate was administered orally in gelatin capsules to groups of 2 male and 2 female beagle dogs at dose levels of 0 (control), 0.43, 1.43 or 7.14 mg/kg/day. The only treatment-related effect observed in males and females in this study was decreased body weight gain. For males, mean absolute body weight gains from 0 to 13 weeks were +3.60, +2.80, +2.20 and +1.15 kg for the control, low, mid and high dose level groups respectively. These gains corresponded to 78%, 61% and 32% of the male control group (100%) for the low, mid and high dose level groups respectively. For females, the comparable mean absolute body weight gains were +2.90, +2.05, +1.75 and +0.55 kg. These gains corresponded to 71%, 60% and 19% of the female control group (100%). Although the % of body weight gain compared to controls was 78% for low dose level males and 71% for low dose level females, the corresponding differences in absolute body weight gains were actually less than 1 kg and since the low dose level animals appeared healthy throughout the entire study and showed no other sign of toxicity, it was concluded that the NOEL for both males and females in this study is 0.43 mg/kg/day and the LOEL is 1.43 mg/kg/day, based on decreased body weight gain. This study is of limited usefulness because only 2 dogs/sex/dose level were used and an insufficient number of tissues was microscopically examined in the control, low and mid dose level groups. (MRID 42869701, 43700201)

In a 13-week subchronic oral study, technical grade bromoxynil octanoate was administered orally in gelatin capsules to groups of 3 male and 3 female beagle dogs at dose levels of 0 (control), 1, 5 or 25 mg/kg/day. No treatment-related effects were observed in either sex at 1 mg/kg/day. At 5 mg/kg/day, occasional panting was noted in both males and females. At 25 mg/kg/day, additional signs of toxicity, observed in both males and females, were panting (after each dose) throughout the study; decreased body weight gain; possibly decreased erythrocyte counts, hemoglobin, and packed cell volume; and increased serum urea nitrogen. The NOEL for both males and females was reported as just under 5 mg/kg/day. (MRID 00061179)

In a 21-day subchronic dermal study, technical grade bromoxynil octanoate was applied to the shaved dorsal skin of 10 male and 10 female New Zealand white rabbits at dose levels of 0 (deionized water control), 30, 300 or 1000 mg/kg/day for 6 hours/day, 5 days/week, for 3 weeks (24-26 days). Treatment with bromoxynil octanoate did not produce any observable systemic effects. Significant dermal irritation, consisting of slight to moderate redness and swelling, cracking and flaking of the skin, was observed at 300 and 1000 mg/kg/day. The NOEL for systemic toxicity is 1000 mg/kg/day, the limit dose for a 21-day study. The NOEL for dermal irritation is 30 mg/kg/day and the LOEL is 300 mg/kg/day. (MRID 42346201)

c. Chronic Toxicity and Carcinogenicity

Table 4 summarizes the available chronic toxicity information. The chronic studies are described in detail following Table 5.

Table 4: Chronic Toxicity Studies

MRID# (Species)	Doses Tested (mg/kg/day)	Systemic Toxicity (mg/kg/day)
Bromoxynil Phenol - Oral		
00096521 (Rat)	0, 0.5, 1.5, 5 (♂, ♀)	NOEL (♂, ♀) = 5 LOEL (♂, ♀) ≻ 5 (not established)
40612501, 41374801 (Rat)	0, 2.6, 8.2, 28 (♂) 0, 3.3, 11.0, 41 (♀)	NOEL (♂) = 2.6 (♀) = 3.3 LOEL (♂) = 8.2 based on ↑ incidence of spongiosis hepatis in the liver (♀) = 11.0 based on ↓ body weight gain
40780301*, 41304701* (Dog)	0, 0.1, 0.3, 1.5, 7.5 (♂, ♀)	Threshold NOEL/LOEL (♂) = 1.5 based on significant↓ body weight gain
Bromoxynil Octanoate - Oral		
Bromoxynil octanoate chronic toxicity studies are satisfied by an acceptable "bridging" study(s) using bromoxynil phenol as the test material.		

* NOEL/LOEL used to determine the RfD or 0.015.

Table 5 summarizes the available carcinogenic toxicity information. The carcinogenicity studies are described in detail following the table.

Table 5: Carcinogenicity Studies

MRID# (Species)	Doses Tested (mg/kg/day)	Non-neoplastic lesions	Neoplastic Lesions
Bromoxynil Phenol - Oral			
00096521 (Rat)	0, 0.5, 1.5, 5 (♂, ♀)	An increased incidence in non-neoplastic lesions was not observed in male and female rats	An increased incidence in neoplastic lesions was not observed in male and female rats.
40612501, 41374801 (Rat)	0, 2.6, 8.2, 28 (♂) 0, 3.3, 11.0, 41 (♀)	(♂) ↑ incidence in histopathological changes in the liver; spongiosis hepatis and foci of eosinophilic cellular alteration.	An increased incidence in neoplastic lesions was not observed in male and female rats.
00068077* (Mouse)	0, 1.3, 3.9, 13 (♂, ♀)	(♂) ↑ incidence in hyperplastic nodules in the liver.	(♂) ↑ incidence in hepatocellular combined adenomas/carcinomas (♀) Doses too low to assess carcinogenic potential.
43245501*, 43311701* (Mouse)	0, 3.1, 12, 46 (♂) 0, 3.7, 14, 53 (♀)	(♂, ♀) ↑ liver weights, diffusely dark livers, ↑ incidence in hepatocellular centrilobular lesions; hypertrophy, degeneration/necrosis and pigmentation in hepatocytes and Kupffer cells.	(♂) ↑ incidence in hepatocellular adenomas, carcinomas and combined adenomas/carcinomas (♀) ↑ incidence of hepatocellular carcinomas and combined adenomas/carcinomas.
Bromoxynil Octanoate - Oral			
Bromoxynil octanoate carcinogenicity studies are satisfied by an acceptable "bridging" study(s) using bromoxynil phenol as the test material.			

*The weight-of-evidence carcinogenicity classification and risk quantification was based primarily on these studies.

Bromoxynil Phenol

In a 12-month chronic oral toxicity study, technical grade bromoxynil phenol was administered in gelatin capsules to groups of 6 male and 6 female beagle dogs at dose levels of 0 (control), 0.1, 0.3, 1.5 or 7.5 mg/kg/day. At the highest dose level tested (7.5 mg/kg/day), the following treatment related effects were observed in both male and female dogs: increased incidences of salivation, panting, liquid feces and pale gums; statistically significant decreased body weight gain over entire duration of study, but particularly during first 8 weeks of study; statistically significant decreased erythrocytes (RBC), hemoglobin (Hb) and packed cell volume (PCV); statistically significant increased urea nitrogen; increased absolute liver weights and liver/body weight ratios. At 1.5 mg/kg/day, a statistically significant decreased body weight gain over the entire duration of study was observed in the male dogs. Other "effects" at this same dose level were marginal, inconsistent and of equivocal toxicological significance. These effects included panting; decreased RBC, Hb and PCV; increased urea nitrogen; and increased absolute and relative liver weights in males and panting and increased absolute and relative liver weights in females. No treatment related gross or histopathological changes were observed in any organs in this study. The dose level of 1.5 mg/kg/day is considered to be a threshold NOEL/LOEL for both male and female dogs in this study. (MRID #40780301, 41304701)

In a 120-week combined chronic feeding/carcinogenicity study, technical grade bromoxynil phenol was administered in the diet to groups of 60 male and 60 female Fischer 344 rats at dose levels of 0 (control), 10, 30 or 100 ppm (equivalent to 0, 0.5, 1.5 or 5 mg/kg/day). Ten rats/sex/dose level were sacrificed and examined at 12 months. An increase in absolute liver weights of the high dose female rats at the 12-month interim sacrifice was considered to be of little concern since a similar increase was not observed at the 120-week terminal sacrifice. No other effects of any kind in either the male or female rats were observed. The NOEL for systemic effects is 100 ppm (5 mg/kg/day) for both male and female rats. An increased incidence of neoplasms was not observed in the male or female rats in this study; however, the dose levels were determined to be too low to assess carcinogenic potential. (MRID 00096521)

In a 2-year combined chronic feeding/carcinogenicity study, technical grade bromoxynil phenol was administered in the diet to Sprague Dawley rats at dose levels of 0 (control), 60, 190 or 600 ppm (0, 2.6, 8.2 or 28 mg/kg/day in males and 0, 3.3, 11.0 or 41 mg/kg/day in females). Groups of 105 male and 105 female rats were given the control diet and groups of 70 male and 70 female rats were given diets containing bromoxynil phenol. Fifteen rats/sex/dose level were sacrificed and examined at 12 months. In male rats, histopathological changes were observed in the liver at 190 ppm (spongiosis hepatis) and at 600 ppm (spongiosis hepatis and foci of eosinophilic cellular alteration). Decreased body weight gain was also noted in male rats at 600 ppm. In female rats, decreased body weight gain was observed at 190 ppm and 600 ppm. No neoplastic lesions were associated with treatment. For male rats, the systemic NOEL is 60 ppm (2.6 mg/kg/day) and the systemic LOEL is 190 ppm (8.2 mg/kg/day), based on an increased incidence of spongiosis hepatis in the liver. For female rats, the systemic NOEL is 60 ppm (3.3 mg/kg/day) and the systemic LOEL is 190 ppm (11.0 mg/kg/day), based on decreased body weight gain. An increased incidence of neoplasms were not observed in the male or female rats. Dose levels used in this study were determined to be sufficiently high to assess carcinogenic potential. (MRID 40612501, 41374801)

In an 18-month carcinogenicity study, technical grade bromoxynil phenol was administered in the diet to groups of 60 male and 60 female Swiss albino mice at dose levels of 0 (control), 10, 30 or 100 ppm (equivalent to 0, 1.3, 3.9 or 13 mg/kg/day). A dose-related increased incidence of liver adenomas/carcinomas combined was observed in the male mice. The increase was statistically significant at 100 ppm. The liver tumor response in male mice was based on both benign and malignant tumors with the carcinomas contributing to almost one-half of the total adenomas/carcinomas at the mid- and high-dose levels. For male mice, the percentage incidences of adenomas were 4%, 8%, 6% and 9%; the percentage incidences of carcinomas were 0%, 0%, 4% and 8%; and the percentage incidences of adenomas/carcinomas combined were 4%, 8%, 10% and 17% for the 0, 10, 30 and 100 ppm groups, respectively. The incidences of hyperplastic nodules in male mice, some of which may have been adenomas, were also increased at the mid- and high-dose levels. Percentage incidences were 4%, 4%, 10% and 9% for the 0, 10, 30 and 100 ppm groups, respectively. An increased incidence of neoplasms was not observed in female mice; however, dose levels for the female mice in this study were determined to be too low to assess carcinogenic potential. (MRID 00068077)

In an 18-month carcinogenicity study, groups of 60 male and 60 female CD-1 mice were given technical grade bromoxynil phenol in the diet at dose levels of 0 (control), 20, 75 or 300 ppm (0, 3.1, 12 or 46 mg/kg/day in males and 0, 3.7, 14 or 53 mg/kg/day in females). Mortality, body weights and food consumption were not affected by treatment. The liver was the target organ. At 300 ppm, treatment related increased liver weights, increased incidences of diffusely dark livers, and increased incidences of non-neoplastic microscopic lesions in the livers of both male and female mice were observed. Histopathologic lesions in the liver included hepatocellular centrilobular hypertrophy, hepatocellular degeneration/necrosis, and pigment in hepatocytes and Kupffer cells. Similar non-neoplastic lesions were also observed in the livers of some male and female mice at 75 ppm. The LOEL for non-carcinogenic effects in this study for both male and female mice is 75 ppm and the NOEL is 20 ppm. Treatment related increased incidences of hepatocellular adenomas, carcinomas, and adenomas/carcinomas combined were observed in the male mice at all dose levels in this study. For male mice, the percentage incidences of adenomas were 6%, 16%, 20% and 19%; the percentage incidences of carcinomas were 4%, 16%, 4% and 21%; and the percentage incidences of adenomas/carcinomas combined were 9%, 31%, 24% and 40% for the 0, 20, 75 and 300 ppm groups, respectively. Subsequent to the original pathology reading, liver sections from all male mice in the study were also evaluated by a second independent pathologist. Similar results were obtained in the second pathology evaluation. For female mice given 300 ppm, slightly increased incidences of hepatocellular carcinomas and of adenomas/carcinomas combined also were considered to be related to treatment with bromoxynil phenol. For female mice, the percentage incidences of carcinomas were 0%, 2%, 0% and 10%; and the percentage incidences of adenomas/carcinomas combined were 4%, 4%, 4% and 17% for the 0, 20, 75 and 300 ppm groups, respectively. Liver sections from female mice in this study were not reevaluated by the independent pathologist. (MRID 43245501, 43311701)

Bromoxynil Octanoate

The Agency has determined that bromoxynil octanoate is toxicologically equivalent to bromoxynil (phenol) with respect to certain oral toxicity studies (HED RfD Peer Review Committee, February 29, 1996). It was concluded that some of the toxicology studies using bromoxynil (phenol) as the test material may be used for the purpose of satisfying the study requirements for bromoxynil octanoate. Hence, there are no required chronic toxicity studies nor carcinogenicity studies in which bromoxynil octanoate was the test material.

d. Developmental Toxicity

Table 6 summarizes the available developmental toxicity information. The developmental studies are described in detail following the table.

Table 6: Developmental Toxicity Studies

MRID (Species)	Doses Tested (mg/kg/day)	Maternal Toxicity (mg/kg/day)	Developmental Toxicity (mg/kg/day)
Bromoxynil Phenol - Oral			
40466802 (Rat)	0, 4, 12.5, 40 (♀)	NOEL = 12.5 LOEL = 40 based on ↓ body weight gain, ↓ food consumption	NOEL = 4 LOEL = 12.5 based on↑ incidence of supernumerary ribs, ↑ post implantation loss
00116558* (Rat)	0, 5, 15, 35 (♀)	NOEL = 5 LOEL = 15 based on ↓ body weight gain	NOEL ≺ 5 (not established) LOEL = 5 based on ↑ incidence of supernumerary ribs
Rogers et al. 1991 (Rat)	0, 1.7, 5, 15 (♀)	NOEL = 5 LOEL = 15 based on ↓ body weight gain, ↑ liver weights	NOEL = 5 LOEL = 15 based on ↑ incidence of supernumerary ribs
00138149 (Rabbit)	0, 15, 30, 60 (♀)	NOEL = 15 LOEL = 30 based on ↓ body weight gain, ↓ food consumption	NOEL ≺ 15 (not established) LOEL = 15 based on ↑ incidence of supernumerary ribs
00142779 (Rabbit)	0, 30, 45, 60 (♀)	NOEL = 45 LOEL = 60 based on ↑ mortality, anorexia, blood discharge	NOEL ≺ 30 (not established) LOEL = 30 based on ↓ fetal weights
Rogers et al. 1991 (Mouse)	0, 11, 32, 96 (♀)	NOEL = 11 LOEL = 32 based on ↑ mortality, ↑ liver weights	NOEL = 32 LOEL = 96 based on ↑ incidence of supernumerary ribs, ↓ fetal weights, ↑ unossified caudal vertebrae
Bromoxynil Phenol - Dermal			
40935101, 41307801 (Rabbit)	0, 10, 50, 150 (♀)	NOEL = 50 LOEL = 150 based on ↓ body weight gain	NOEL = 10 LOEL = 50 based on ↑ in agenesis of intermediate lobe of the lung, ↑ holes in parietal bone
40881201, 40883601 (Rat)	0, 5, 10, 50, 100 (♀)	NOEL = 50 LOEL = 100 based on ↓ body weight gain, ↓ food consumption	NOEL = 10 LOEL = 50 based on ↑ incidence of supernumerary ribs
Bromoxynil Octanoate - Oral			
Rogers et al. 1991 (Rat)	0, 2.4, 7.3, 21.8 (♀)	NOEL = 7.3 LOEL = 21.8 based on ↓ body weight gain, ↑ liver weights	NOEL = 7.3 LOEL = 21.8 based on ↑ incidence of supernumerary ribs, ↓ fetal weights
Bromoxynil Octanoate - Dermal			
41163301 (Rat)	0, 2, 5, 10, 15, 20, 75 (♀)	NOEL = 15 LOEL = 20 based on ↓ body weight gain, ↓ food consumption	NOEL = 10 LOEL = 15 based on ↑ incidence of supernumerary ribs
41471901, 42183901 (Rabbit)	0, 5, 10, 15, 20, 40, 80 (♀)	NOEL = 80 LOEL ≻ 80 (not established)	NOEL = 80 LOEL ≻ 80 (not established)

*NOEL used in the acute dietary risk assessment for the subpopulation of females 13+.

Bromoxynil Phenol

In an oral developmental toxicity study, technical grade bromoxynil phenol was administered to groups of 22 pregnant Sprague Dawley rats by gavage at doses of 0 (control), 4, 12.5 or 40 mg/kg/day on gestation days 6-15, inclusive. The developmental toxicity NOEL is 4 mg/kg/day. A dose-related increased incidence of supernumerary (14th) ribs was observed at the developmental toxicity LOEL of 12.5 mg/kg/day. Increased post-implantation loss was also observed at 12.5 mg/kg/day. At 40 mg/kg/day, the following additional effects were observed in the offspring: reduced fetal weight, increased numbers of small fetuses, and increased incidences of soft tissue and skeletal abnormalities (including anophthalmia, microphthalmia, short renal papilla, and spinal and thoracic bone abnormalities). The maternal toxicity NOEL is 12.5 mg/kg/day and the maternal toxicity LOEL is 40 mg/kg/day, based on decreased body weight gain throughout most of the treatment and post-treatment period and decreased food consumption during the treatment period. (MRID 40466802)

In an oral developmental toxicity study, groups of 28 pregnant Sprague Dawley rats received 0 (control), 5, 15 or 35 mg/kg/day of technical grade bromoxynil phenol by gavage on gestation days 5-17, inclusive. No developmental toxicity NOEL was determined in this study (below 5 mg/kg/day). At the LOEL of 5 mg/kg/day, a dose-related increased incidence of supernumerary ribs was observed. At the high dose of 35 mg/kg/day, additional effects included an increased incidence of late intrauterine deaths, decreased fetal body weights and an increase in the total incidence of minor anomalies. The maternal toxicity NOEL is 5 mg/kg/day and the maternal toxicity LOEL is 15 mg/kg/day, based on decreased body weight gain. At 35 mg/kg/day, 6/28 dams died between days 7 and 14 of gestation. (MRID 00116558)

Groups of 20-25 pregnant Sprague Dawley rats were given 0 (control), 1.7, 5 or 15 mg/kg/day of technical grade bromoxynil phenol by oral gavage on gestation days 6-15, inclusive. In the offspring, the litter incidences of supernumerary ribs were 30%, 60%, 50% and 90% in the control, 1.7, 5 and 15 mg/kg/day groups, respectively. The percentages of litters with supernumerary ribs were significantly increased at the 1.7 and 15 mg/kg/day dose levels. However, the increase at 1.7 mg/kg/day was not considered to be biologically significant. The developmental toxicity NOEL is 5 mg/kg/day and the developmental toxicity LOEL is 15 mg/kg/day, based on an increased incidence of supernumerary ribs. The maternal toxicity NOEL is 5 mg/kg/day and the maternal toxicity LOEL is 15 mg/kg/day, based on decreased body weight gain and increased liver weights. No consistent effects were seen on thymus, spleen or adrenal weights suggesting there was no generalized stress response in the dams. (Rogers, Francis, Barbee et al., 1991)

In an oral developmental toxicity study, technical grade bromoxynil phenol was administered to groups of 18 or more pregnant New Zealand white rabbits by gavage at doses of 0 (control), 15, 30 or 60 mg/kg/day on days 5-20 of gestation. A high incidence (on a litter basis) and a dose-related increased incidence (on a fetal basis) of fully formed bilateral 13th ribs and an increased incidence of all forms of supernumerary ribs were observed at 15, 30 and 60 mg/kg/day. At 60 mg/kg/day, the following additional effects were also observed: increased post-implantation loss (due primarily to

5 totally resorbed litters), decreased fetal weights, and increased numbers of litters and numbers of fetuses with major malformations (including hydrocephalus, anophthalmia, microphthalmia and defects in skull ossification). The incidence of total minor anomalies was also increased at 60 mg/kg/day. The NOEL for developmental toxicity was not determined in this study (below 15 mg/kg/day). The developmental toxicity LOEL is 15 mg/kg/day, based on the increased incidence of supernumerary ribs. The maternal toxicity NOEL is 15 mg/kg/day and the maternal toxicity LOEL is 30 mg/kg/day, based on reduced body weight gain and reduced food consumption during the treatment period. There were no deaths or clinical signs of toxicity associated with treatment. (MRID 00138149)

In an oral developmental toxicity study, groups of 22-23 pregnant New Zealand white rabbits were given 0 (control), 30, 45 or 60 mg/kg/day of technical grade bromoxynil phenol by gavage on gestations days 6-18, inclusive. The number of fetuses with decreased body weights (30% below control mean weight) was significantly increased at all dose levels, At 45 and 60 mg/kg/day, a dose-related increase in supernumerary ribs also was observed. At 60 mg/kg/day, several vertebral and thoracic bone abnormalities, including fused ribs, scoliosis, extra ribs, thoracic centrum misshapen and incomplete ossification of sternebrae, were observed. A NOEL for developmental toxicity was not determined in this study (below 30 mg/kg/day). The developmental toxicity LOEL is 30 mg/kg/day, based on decreased fetal weights. The maternal toxicity NOEL is 45 mg/kg/day and the maternal toxicity LOEL is 60 mg/kg/day, based on increased mortality (7/23 dams died at this dose level) and other clinical signs of toxicity, including anorexia and discharge of blood. (MRID 00142779)

Groups of 16-35 pregnant Swiss Webster (CD-1) mice were given 0 (control), 11, 32 or 96 mg/kg/day of technical grade bromoxynil phenol by oral gavage on gestation days 6-15, inclusive. In the offspring, the litter incidences of 14th ribs were 50%, 28%, 56% and 81% in the control, 11, 32 and 96 mg/kg/day groups, respectively. The increased incidence was statistically significant at the high dose. Also at 96 mg/kg/day, decreased fetal weights and decreased numbers of fetuses with ossified caudal vertebrae were observed. The developmental toxicity NOEL is 32 mg/kg/day and the developmental toxicity LOEL is 96 mg/kg/day, based on increased incidence of 14th ribs, decreased fetal weights and decreased numbers of fetuses with ossified vertebrae. The maternal toxicity NOEL is 11 mg/kg/day and the maternal toxicity LOEL is 32 mg/kg/day, based on increased mortality and increased liver weights. No consistent effects were seen on thymus, spleen or adrenal weights suggesting there was no generalized stress response in the dams. (Rogers, Francis, Barbee et al., 1991)

In a dermal developmental toxicity study, bromoxynil phenol (solubilized in water containing 50 mg/ml sodium hydroxide and 20% triethylene glycol) was applied to groups of 20 pregnant New Zealand white rabbits at dose levels of 0 (control), 10, 50 or 150 mg/kg/day for 6 hours/day on gestation days 6-18, inclusive. The results in this study were compromised by 25 rabbits possibly being improperly dosed on days 6 and/or 7 of gestation. The developmental toxicity NOEL is 10 mg/kg/day and the developmental toxicity LOEL is 50 mg/kg/day, based on an apparent increase in agenesis of the intermediate lobe of the lung and on an increase in holes in the parietal portion of the

skull. Lung agenesis has not been observed in other studies with bromoxynil and its incidence in historical controls is highly variable. The incidence of supernumerary ribs was not affected in this study. The maternal toxicity NOEL is 50 mg/kg/day and the maternal toxicity LOEL is 150 mg/kg/day, based on decreased body weight gain. Because of flaws in the execution of this study, the results have been interpreted with considerable caution and the NOELs and LOELs are considered to be tentative. (MRID 40935101, 41307801)

In a dermal developmental toxicity study, bromoxynil phenol (solubilized in water containing 50 mg/ml sodium hydroxide and 20% triethylene glycol) was applied to groups of 23 pregnant Sprague Dawley rats at dose levels of 0 (control), 5, 10, 50 or 100 mg/kg/day for 6 hours/day on gestation days 6-15, inclusive. A dose-related increased incidence of supernumerary (14th) ribs was observed in this study at 10, 50 and 100 mg/kg/day. At 10 mg/kg/day, however, the increased incidence was not statistically significant compared to the concurrent control group and was within the historical control range. The developmental toxicity NOEL is 10 mg/kg/day and the developmental toxicity LOEL is 50 mg/kg/day, based on increased 14th ribs. The maternal toxicity NOEL is 50 mg/kg/day and the maternal toxicity LOEL is 100 mg/kg/day, based on decreased body weight gain and decreased food consumption during the treatment period. No deaths or clinical signs, including skin irritation, were attributed to treatment with the test material in this study. (MRID 40881201, 40883601)

Bromoxynil Octanoate

In an oral developmental toxicity study, technical grade bromoxynil octanoate was administered to groups of 17-20 pregnant Sprague Dawley rats by gavage at doses of 0 (control), 2.4, 7.3 or 21.8 mg/kg/day on gestation days 6-15, inclusive. In the offspring, the litter incidences of 14th ribs were 29%, 40%, 37% and 65% in the control, low, mid and high dose groups, respectively. The increased incidence was statistically significant at the high dose. Reduced fetal weights were also observed in the high dose group. The developmental toxicity NOEL is 7.3 mg/kg/day and the developmental toxicity LOEL is 21.8 mg/kg/day, based on an increased incidence of 14th ribs and on reduced fetal weights. The maternal toxicity NOEL is 7.3 mg/kg/day and the maternal toxicity LOEL is 21.8 mg/kg/day, based on decreased body weight gain and increased liver weights. No consistent effects were seen on thymus, spleen or adrenal weights suggesting there was no generalized stress response in the dams. (Rogers, Francis, Barbee et al., 1991)

In a dermal developmental toxicity study, bromoxynil octanoate (Buctril formulation diluted in water) was applied to groups of 25 pregnant Sprague Dawley rats at dose levels of 0 (Buctril formulation inerts and water controls), 2, 5, 10, 15, 20 or 75 mg a.i./kg/day for 6 hours/day on gestation days 6-15, inclusive. The developmental toxicity NOEL is 10 mg a.i./kg/day. A dose-related increased incidence of supernumerary (14th) ribs was observed at the developmental toxicity LOEL of 15 mg a.i./kg/day. At 20 and 75 mg a.i./kg/day, the incidences of supernumerary ribs were increased still further. Skin irritation was observed in the Buctril formulation inerts control and 75 mg a.i./kg/day treatment groups. The maternal toxicity NOEL is 15 mg a.i./kg/day and the maternal toxicity LOEL is 20 mg a.i./kg/day, based on decreased body weight gain and decreased food consumption during the treatment period. (MRID 41163301)

In a dermal developmental toxicity study, groups of 20 pregnant New Zealand white rabbits were treated with bromoxynil octanoate (Buctril formulation diluted in water) at dose levels of 0 (Buctril formulation inerts and water controls), 5, 10, 15, 20, 40 or 80 mg a.i./kg/day for 6 hours/day on gestation days 6-18, inclusive. Incidences of 13th ribs were high in control and all treatment groups. A dose-response relationship, however, was not evident and it was concluded that no adverse effects on offspring development were observed. The developmental toxicity NOEL is 80 mg a.i./kg/day. A developmental toxicity LOEL was not determined in this study (above 80 mg a.i./kg/day). Significant skin irritation was observed in the Buctril formulation inerts control and all treatment groups. At 15 mg a.i./kg/day and higher, the majority of rabbits displayed erythema, fissuring and desquamation. The frequency and severity of skin irritation increased with increasing concentration of Buctril. Desquamation persisted for most of the post-treatment period. Skin irritation, however, did not appear to adversely affect maternal well-being. No systemic toxicity was observed in the dams at any dose level. The NOEL for systemic maternal toxicity is 80 mg a.i./kg/day. A LOEL for systemic maternal toxicity was not determined in this study (above 80 mg a.i./kg/day). (MRID 41471901, 42183901)

e. Reproductive Toxicity

Table 7 summarizes the available reproductive toxicity information. The reproductive studies are described in detail following the table.

Table 7: Reproductive Studies

MRID# (Species)	Doses Tested (mg/kg/day)	Systemic Toxicity (mg/kg/day)	Reproductive Toxicity (mg/kg/day)	Developmental Toxicity (mg/kg/day)
Bromoxynil Phenol - Oral				
41149301 (Rat)	0, 0.8, 4, 21 (♂,♀)	NOEL (♀)= 4 LOEL = 21 based on ↓ body weight gain in F_0 and F_1 (♀) rats, ↑ liver weights (♂,♀)	NOEL (♂,♀) = 21 LOEL (♂,♀) ≻ 21 (highest dose tested)	NOEL = 4 LOEL = 21 based on ↓ body weight gain during lactation, delayed eye opening
00064815 (Rat)	0, 1.5, 5, 15 (♂,♀)	NOEL (♂,♀) = 1.5 LOEL = 5 based on ↓ body weight gain in F_1 and F_2 (♂,♀) rats	NOEL (♂,♀) = 15 LOEL (♂,♀) ≻ 15 (highest dose tested)	NOEL = 5 LOEL = 15 based on ↓ body weight gain in F_2 generation
Bromoxynil Octanoate - Dermal				
41667401 (Rat)	0, 25, 50, 100 (♂,♀)	NOEL (♂) = 25 LOEL (♂) = 50 based on ↓ body weight gain	NOEL (♂) = 50 LOEL (♂) = 100 based on ↓ prostate weight gland	NOEL = 100 LOEL ≻ 100 (not established)

Bromoxynil Phenol

In a 2-generation reproduction study, technical grade bromoxynil phenol was administered in the diet to groups of 24 male and 24 female Sprague Dawley rats at dose levels of 0 (control), 10, 50 or 250 ppm (approximately 0, 0.8, 4 or 21 mg/kg/day) during 14 weeks prior to mating. No

reproductive toxicity was observed in this study at any dose level. The NOEL for reproductive toxicity is 250 ppm (21 mg/kg/day) and the LOEL for reproductive toxicity is greater than 250 ppm (HDT). The NOEL for developmental toxicity in offspring is 50 ppm (4 mg/kg/day) and the LOEL is 250 ppm (21 mg/kg/day), based on decreased body weight gain during lactation and delayed eye opening. The NOEL for systemic toxicity in adult rats is 50 ppm (4 mg/kg/day) and the LOEL is 250 ppm (21 mg/kg/day), based on decreased body weight gain in F0 and F1 females before mating, during gestation and lactation and at study termination. In addition, possibly increased liver weights were observed in both male and female adults. (MRID 41149301)

In a 3-generation reproduction study, technical grade bromoxynil phenol was administered in the diet to groups of 10 male and 20 female Wistar rats at dose levels of 0 (control), 30, 100 or 300 ppm (equivalent to 0, 1.5, 5 or 15 mg/kg/day). Definitive NOELs and LOELs were not determined in this study due to numerous deficiencies in data reporting. The following NOELs and LOELs are therefore tentative. No reproductive toxicity was observed in this study at any dose level. The NOEL for reproductive toxicity is 300 ppm (15 mg/kg/day) and the LOEL for reproductive toxicity is greater than 300 ppm (HDT). The NOEL for developmental toxicity in offspring is 100 ppm (5 mg/kg/day) and the LOEL is 300 ppm (15 mg/kg/day), based on decreased body weight gain, particularly in the F2 generation. The NOEL for systemic toxicity in adult rats is 30 ppm (1.5 mg/kg/day) and the LOEL is 100 ppm (5 mg/kg/day), based on decreased body weight gain in F1 and F2 parents. (MRID 00064815)

Bromoxynil Octanoate

In a specially designed dermal reproduction study, groups of 20 male Crl:CRBR VAF/Plus rats were treated for 6 hours each day for 21 days with bromoxynil octanoate (Buctril formulation diluted in water) at dose levels of 0 (Buctril formulation inerts and water controls), 25, 50 or 100 mg a.i./kg/day. After 21 days of treatment, the male rats were mated with untreated female rats on days 1, 7, 14, 21, 35, 56 or 113 post-exposure. No effects on mating or fertility were observed in the male rats at any dose level. Possibly reduced prostate gland weight on day 1 post-exposure, however, was observed at 100 mg a.i./kg/day. The NOEL for male reproductive toxicity is 50 mg a.i./kg/day (tentative) and the LOEL is 100 mg a.i./kg/day (tentative), based on possibly decreased prostate gland weight. No effects on offspring development were observed. The NOEL for developmental toxicity in offspring is 100 mg a.i./kg/day (HDT) and the LOEL greater than 100 mg a.i./kg/day. The NOEL for systemic toxicity in the adult male rats is 25 mg a.i./kg/day and the LOEL is 50 mg a.i./kg/day, based on decreased body weight gain. At 100 mg a.i./kg/day, possibly increased liver weights were also observed. Significant skin irritation was observed in the control group (Buctril formulation inerts only) and Buctril treated groups, particularly at 100 mg a.i./kg/day. This study is a specially designed study and does not satisfy the requirement for a multigeneration reproduction study in rats (Guideline 83-4). (MRID 41667401)

f. Mutagenicity

Table 8 summarizes the available mutagenicity toxicity information. The mutagenicity studies are described in detail following the table.

Table 8: Mutagenicity Studies

Study	Genotoxic Effect	MRID#
Bromoxynil Phenol		
Other Mutagenic Mechanisms/ *In vitro* unscheduled DNA synthesis	Negative	00115646
Other Mutagenic Mechanisms/ Cell Transformation	Negative	00115647
Other Mutagenic Mechanisms/ *In vitro* Sister Chromatid Exchange (CHO)	Negative (non-activated and activated)	00115648
Gene Mutation/ *In vitro* assay in mammalian cells (mouse lymphoma)	Negative (non-activated) Positive (activated)	00115649
Other Mutagenic Mechanisms/ Bacterial DNA Damage/Repair (E. Coli)	Positive (non-activated and activated)	00115650
Cytogenetics/ *In vitro* assay in mammalian cells (CHO)	Negative (non-activated) Positive (activated)	00115651
Cytogenetics/ *In vivo* mouse micronucleus assay	Negative	00124803
Gene Mutation/ *In vitro* assay in mammalian cells (CHO/HGPRT)	Negative (non-activated and activated)	41995702
Gene Mutation in *Salmonella typhimurium*	Negative (non-activated and activated)	41995701
Cytogenetics/ *In vivo* mouse micronucleus assay	Negative	42092301
Bromoxynil Octanoate		
Gene Mutation in *Salmonella typhimurium*	Negative (non-activated and activated)	43022701
Cytogenetics/ *In vivo* mouse micronucleus assay	Negative	41930802
Other Mutagenic Mechanisms/ *In vitro* unscheduled DNA synthesis	Negative	42078901

Bromoxynil Phenol

In an unscheduled DNA synthesis (UDS) assay, cultures of primary rat hepatocytes were exposed to technical grade bromoxynil phenol at concentrations ranging from 0.1 to 50 ug/ml. At 50 ug/ml, all cells died. At 25 ug/ml, the next highest concentration, cell survival was 31%. Cell survival increased with decreasing concentrations of test material. The positive control (2-acetylaminofluorene) was adequate. Bromoxynil phenol did not cause an appreciable increase in mean net nuclear grain counts compared to the negative solvent control at any of the evaluated concentrations. Bromoxynil phenol did not induce a genotoxic effect in this assay system. (MRID 00115646)

In an in vitro transformation assay, cultures of mouse C3H/10T ½ C18 cells were exposed to technical grade bromoxynil phenol at concentrations ranging from 32.5 to 390 ug/ml. Based on results in a preliminary cytotoxicity study, cell survival at these concentrations was expected to be between 20% and 100%. The positive control, benz(a)pyrene, was satisfactory. After incubation of cell cultures for approximately 6 weeks, a pooled average of Type II and Type III foci/culture was scored as frequency of transformation. The frequency of transformed foci in bromoxynil phenol treated cultures was equal to or less than in the negative solvent control. Bromoxynil phenol did not induce a genotoxic effect in this assay system. (MRID 00115647)

In a sister chromatid exchange (SCE) assay, cultures of Chinese hamster ovary (CHO) cells were exposed to technical grade bromoxynil phenol without metabolic activation at concentrations ranging from 4.67 to 18.7 ug/ml and with metabolic activation (rat S9 mixture) at concentrations ranging from 500 to 900 ug/ml. The solvent used was DMSO. The positive controls (mitomycin for the non-activated system and cyclophosphamide for the activated system) were adequate. After incubation, chromosome preparations were stained and examined. Bromoxynil phenol, without and with metabolic activation, did not induce any significant increases in sister chromatid exchanges. Bromoxynil phenol did not induce a genotoxic effect in this assay system. (MRID 00115648)

In a mouse lymphoma forward mutation assay, cultures of L5178Y TK+/- cells were exposed to technical grade bromoxynil phenol without metabolic activation at concentrations ranging from 15.6 to 250 ug/ml and with metabolic activation (rat S9 mixture) at concentrations of 3.9, 7.8, 15.6, 31.3 or 62.5 ug/ml. The solvent used was DMSO. The positive controls (ethylmethane sulfonate for non-activated system and dimethylnitrosamine for activated system) were satisfactory. After incubation, the mutant frequency was calculated as the ratio of mutant colonies to viable colonies. In the non-activated system, there were no significant increases in mutant frequency at any concentration when compared to that of the untreated and negative solvent controls--even at the highly toxic concentration of 250 ug/ml (9.5% relative growth). Significant increases in the mutant frequency, however, did occur in the activated system at the two highest, most toxic concentrations of test material. At the moderately toxic concentration of 31.3 ug/ml (39.6% relative growth), there was a 2 fold increase in mutant frequency above background levels and at the highly toxic concentration of 62.5 ug/ml (7.9% relative growth), there was a 4.1 fold increase in mutant frequency above background levels. Mutant frequencies in the positive control were greatly in excess of background levels. Bromoxynil phenol did not induce a genotoxic effect in the non-activated portion of this assay, but the dose-related increase in mutant colonies in the activated portion of this assay was considered to be a positive genotoxic response. (MRID 00115649)

In a bacterial DNA repair test using Escherichia coli indicator strains, pol A+ (W3110) and pol A- (p3478), cultures of both indicator strains on agar plates were exposed to technical grade bromoxynil phenol without and with metabolic activation (rat S9 mixture) at concentrations ranging from 1.0 to 10000 ug/plate. The test material was placed in wells of uniform diameter in the center of each agar plate. The solvent used was DMSO. The positive controls (ethylmethane sulfonate and methylmethane sulfonate for the non-activated system and dimethylnitrosamine for the activated system) were adequate. The preferential inhibition of the pol A- strain, relative to the pol A+ strain, was determined by measuring the differential zones of inhibition produced by the test material around each well. Differential zones of inhibition, indicating a mutagenic event (involving DNA polymerase I enzyme), were observed in both the non-activated and activated systems at concentrations from 1000 ug/plate to 10000 ug/plate. A dose-response effect was evident at concentrations from 500 ug/plate (NOEL) to 5000 ug/plate in both systems. At 10000 ug/plate, a dose-response effect may have been obscured by the high level of background cytotoxicity. Bromoxynil phenol induced a positive genotoxic response in both the non-activated and activated portions of this assay. (MRID 00115650)

In an in vitro chromosome aberration assay, cultures of Chinese hamster ovary (CHO) cells were exposed to technical grade bromoxynil phenol without metabolic activation at concentrations ranging from 100 to 1500 ug/ml (8 hour exposure) and from 50 to 500 ug/ml (20 hour exposure). CHO cells were also exposed to test material with metabolic activation (rat S9 mixture) for 2 hours at concentrations ranging from 300 to 1500 ug/ml (trial 1) and at concentration ranging from 1200 to 1600 ug/ml (trial 2). The solvent used was DMSO. The positive controls (mitomycin C for the non-activated system and cyclophosphamide for the activated system) were adequate. After incubation, chromosome preparations were stained and examined. In the non-activated system, there was no significant increase in chromosome aberrations when compared to the untreated and negative solvent controls. In the activated system, however, significant increases in chromosome aberrations above background levels were observed. In trial 1 at 1500 ug/ml, but not at lower concentrations, a statistically significant increase in chromosome aberrations was observed. These aberrations included numerous simple chromosome breaks and chromatid breaks and also complex aberrations such as chromatid interchanges. In trial 2 at all concentrations (1200 to 1600 ug/ml), significant increases in chromosome aberrations, including simple breaks and complex chromatid aberrations, were again observed. Bromoxynil phenol did not induce a genotoxic effect in the non-activated portion of this assay, but the significant increase in chromosome damage in the activated portion of this assay at concentrations equal to and above 1200 ug/ml was considered to be a positive genotoxic response. (MRID 00115651)

In an in vivo micronucleus assay, two doses of bromoxynil phenol were administered orally by gavage on two consecutive days to groups of 5 male and 5 female CD-1 mice at dose levels of 0 (control), 21.6, 69.0 or 215 mg/kg/day. Dose levels were based on a previously determined LD50 of 431 $\pm$ 177 mg/kg/day under similar conditions. Bone marrow was taken 6 hours after the second dose and examined for micronuclei in polychromatic erythrocytes (PCE). Normochromatic erythrocytes (NCE) were also counted and the NCE/PCE ratio was recorded for each animal. The positive control (cyclophosphamide) was satisfactory. At 215.5 mg/kg/day, 5 mice died shortly after dosing. At 215.5 (in survivors) and 69.0 mg/kg/day, depressed hematopoiesis, evidenced by shifts in the NCE/PCE ratio, indicated target cell cytotoxicity. No increased frequencies of micronuclei were observed at any dose level in the bone marrow cells of treated mice. Bromoxynil phenol did not induce a clastogenic effect in this assay system. (MRID 00124803)

In a forward mutation assay, cultures of Chinese hamster ovary (CHO)/HGPRT locus cells were exposed to technical grade bromoxynil phenol without and with metabolic activation (rat S9 mixture) at concentrations ranging from 100 to 1000 ug/ml. The solvent used was DMSO. The positive controls (5-bromo-2'-deoxyuridine for non-activated system and 3-methylcholanthrene for activated system) were adequate. After incubation, mutation frequencies were determined and compared to the negative solvent control. In the non-activated system, the concentration of 1000 ug/ml was severely toxic (4.5% relative growth). In the activated system, concentrations of 800 ug/ml and higher were also severely toxic ($\leq$ 2.7% relative growth). Cell survival increased with decreasing concentrations of test material. In the non-activated system, the test material did not significantly increase the mutation frequency at the HGPRT locus. In the activated system, increases in the mutation frequency were observed at several concentrations of test material, but were not dose-

related, did not exceed the testing laboratory's acceptable background frequency, and therefore were not considered to be mutagenic events. Bromoxynil phenol, without and with metabolic activation, did not induce a genotoxic effect in this assay system. (MRID 41995702)

In a Salmonella/mammalian microsome reverse mutation assay (Ames study), strains TA98, TA100, TA1535, TA1537 and TA1538 were exposed to technical grade bromoxynil phenol without metabolic activation at concentrations ranging from 3.33 to 1000 ug/plate and with metabolic activation (rat S9 mixture) at concentrations ranging from 10.0 to 3330 ug/plate. Cytotoxicity was observed in the majority of strains exposed to 1000 ug/plate in the non-activated system and in most strains exposed to 1000 ug/plate and higher in the activated system. The solvent used was DMSO. The several positive controls (sodium azide, 2-nitrofluorene and ICR 191 for the non-activated system and 2-aminoanthracene for the activated system) were satisfactory. After incubation, mean numbers of revertant mutant colonies per plate were determined for each strain. Noncytotoxic concentrations of bromoxynil phenol did not significantly increase the number of revertant mutant colonies per plate over background levels in any of the 5 strains tested, without or with metabolic activation, at any of the evaluated concentrations. Bromoxynil phenol, without and with metabolic activation, did not induce a genotoxic effect in this assay system. (MRID 41995701)

In an <u>in vivo</u> micronucleus assay, single doses of technical grade bromoxynil phenol were administered orally by gavage to groups of 5 male and 5 female CD-1 mice at dose levels of 0 (control), 35, 70 or 105 mg/kg. Dose levels were based on the results in a previously conducted toxicity study in which dose-related mortalities of up to 80% were observed between 125 and 275 mg/kg under similar conditions. Bone marrow cells, harvested at 24, 48 and 72 hours postexposure in the high dose group and at 24 hours postexposure in the mid and low dose groups, were examined for the frequency of micronuclei in polychromatic erythrocytes (PCE). Normochromatic erythrocytes (NCE) were also counted and the PCE/NCE ratio was recorded for each animal. The positive control (cyclophosphamide) was adequate. At 105 mg/kg, 1 mouse died. No evidence of a cytotoxic response, as evidenced by an altered PCE/NCE ratio, was observed in the bone marrow cells of either sex at any dose level or sacrifice time, but the single mortality at the high dose level was consistent with the results in the previously conducted toxicity study and indicated that an appropriately high dose level was evaluated in the micronucleus assay. No increased frequencies of micronuclei were observed at any dose level or sacrifice time in the bone marrow cells of treated male or female mice. Bromoxynil phenol did not induce a clastogenic effect in this assay system. (MRID 42092301)

<u>Bromoxynil Octanoate</u>

In a Salmonella/mammalian microsome reverse mutation assay (Ames study), strains TA98, TA100, TA1535, TA1537 and TA1538 were exposed to technical grade bromoxynil octanoate without and with metabolic activation (rat S9 mixture) at concentrations ranging from 33 to 10000 ug/plate. Compound precipitation was observed at 10000 ug/plate and minimal to moderate cytotoxicity was observed in the majority of strains exposed to 3333 ug/plate and higher. The solvent used was DMSO. The several positive controls (sodium azide, 2-nitrofluorene and 9-aminoacridine for the non-activated system and 2-aminoanthracene for the activated system) were satisfactory.

After incubation, mean numbers of revertant mutant colonies per plate were determined for each strain. Noncytotoxic concentrations of bromoxynil phenol did not significantly increase the number of revertant mutant colonies per plate over background levels in any of the 5 strains tested. Bromoxynil octanoate, without and with metabolic activation, did not induce a genotoxic effect in this assay system. (MRID 43022701)

In an in vivo micronucleus assay, single doses of technical grade bromoxynil octanoate were administered orally by gavage to groups of 5 male CD-1 mice at dose levels up to 183 mg/kg and to groups of 5 female CD-1 mice at dose levels up to 267 mg/kg. Dose levels were based on the results in previously conducted toxicity studies in which the LD50 for males and females were determined to be 262 and 382 mg/kg, respectively. Bone marrow cells, harvested at 24, 48 and 72 hours postexposure in the high dose group and at 24 hours postexposure in the mid and low dose groups, were examined for the frequency of micronuclei in polychromatic erythrocytes (PCE). Normochromatic erythrocytes (NCE) were also counted and the PCE/NCE ratio was recorded for each animal. The positive control (cyclophosphamide) was adequate. At 183 mg/kg, no male mice died, but at 267 mg/kg, 2 female mice died. No evidence of a cytotoxic response was observed in the bone marrow cells of either sex at any dose level or sacrifice time, but the mortalities at the high dose level for females were consistent with the results in the previously conducted toxicity study and indicated that an appropriately high dose level was evaluated. In males, although no deaths occurred, it was doubtful that the use of a higher lethal dose would have affected the outcome of the study. No increased frequencies of micronuclei were observed at any dose level or sacrifice time in the bone marrow cells of treated male or female mice. Bromoxynil octanoate did not induce a clastogenic effect in this assay system. (MRID 41930802)

In an unscheduled DNA synthesis (UDS) assay, cultures of primary rat hepatocytes were exposed to technical grade bromoxynil octanoate at concentrations ranging from 0.98 to 15.63 ug/ml. Higher concentrations ($\geq$ 31.25 ug/ml) were cytotoxic. The solvent used was DMSO. The positive control (2-acetylamino-fluorene) was adequate. Bromoxynil octanoate did not induce an appreciable increase in mean net nuclear grain counts compared to the negative solvent control at any of the evaluated concentrations. Bromoxynil octanoate did not induce a genotoxic effect in this assay system. (MRID 42078901)

g. Neurotoxicity

No potential for neurotoxicity has been observed in any of the animal studies with bromoxynil phenol. Neither a delayed neurotoxicity study in hens (Guideline 81-7) nor a 28-day delayed neurotoxicity in hens (Guideline 82-6) is required. The requirements for an acute neurotoxicity study in rats (Guideline 81-8) and a 90-day neurotoxicity study in rats (Guideline 82-7) are reserved.

h. Immunotoxicity

The requirement for immunotoxicity testing (Guideline 85-7) is reserved for both the bromoxynil phenol and octanoate. Information may be required at a later time.

i. Metabolism

Bromoxynil Phenol

No general metabolism study (Guideline 85-1) is available in which bromoxynil phenol was the test material. The requirement for a general metabolism study on bromoxynil phenol, however, has been waived since sufficient information on the pharmacokinetics and metabolism of bromoxynil phenol *per se* has been derived from general metabolism studies on bromoxynil octanoate and bromoxynil heptanoate. Refer to the discussion under l. Toxicity Equivalence below for additional information on the bromoxynil heptanoate metabolism study.

Bromoxynil Octanoate

The absorption, distribution, excretion and metabolism of bromoxynil octanoate were studied in male and female Sprague Dawley rats given single oral doses of ^{14}C-bromoxynil octanoate by gavage at dose levels of 2 or 20 mg/kg or at a dose level of 2 mg/kg following 14 days of unlabeled bromoxynil octanoate administered by oral gavage at a dose level of 2 mg/kg/day. Results were similar regardless of the dosing regimen. The rate of absorption was moderate in both males and females. Peak plasma concentrations of radioactivity were not reached until 7-10 hours after dosing. Radioactivity was widely distributed in most tissues. The highest concentrations were observed in blood, plasma, liver, kidneys and thyroid (especially in females). Levels of radioactivity in tissues were generally higher in females than in males. Most radioactivity was excreted in the urine (about 84-89% in males and 76-80% in females at 7 days) and considerably lesser amounts in the feces (about 6-10% in both males and females at 7 days). Excretion was more rapid in males than in females. Retention of radioactivity in tissues after 7 days was about 2-3% in males and 7-9% in females. Essentially all bromoxynil octanoate was rapidly and nearly completely converted to bromoxynil phenol via ester hydrolysis. In special studies, the only chemical species identified in tissues was bromoxynil phenol *per se*; no bromoxynil octanoate was identified in tissues. In urine, the only major species was free and conjugated bromoxynil phenol with no bromoxynil octanoate present. In feces, however, some bromoxynil octanoate was identified. (MRID 00154756, 00154757, 42901001)

j. Dermal Penetration

The dermal absorption for the bromoxynil octanoate is 10.32% and the bromoxynil phenol is 1.92% based on studies (40854602, 40854603) summarized below. The occupational cancer risk was determined using the absorption factor of 10% (rounded from 10.32%).

Bromoxynil Phenol

^{14}C-Bromoxynil phenol, solubilized in water with sodium hydroxide, was topically applied to the skin of male Sprague Dawley rats at doses of 0.10, 1.0 or 10.0 mg/rat for durations of exposure of 0.5, 1, 2, 4, 10 or 24 hours (4 rats/dose/duration of exposure). The quantity of radioactivity

absorbed increased with dose and duration of exposure. Percent dermal absorption at 10 hours was 1.92%, 1.74% and 1.24% for doses of 0.10, 1.0 and 10.0 mg/rat respectively. Following a soap and water wash (at 10 hours), 22.64%, 10.79% and 3.79% of the respective doses remained in/on the skin. Percent dermal absorption at 24 hours was 3.12%, 3.24% and 3.02% for doses of 0.10, 1.0 and 10.0 mg/rat respectively. Following a soap and water wash (at 24 hours), 18.99%, 7.84% and 2.03% of the respective doses remained in/on the skin. (MRID 40854602)

Bromoxynil Octanoate

^{14}C-Bromoxynil octanoate, incorporated into the end-use product Buctril, which contained 33.4% bromoxynil octanoate as the active ingredient, was topically applied to the skin of male Sprague Dawley rats at doses of 0.08, 0.4 or 3.4 mg/rat for durations of exposure of 0.5, 1, 2, 4, 10 or 24 hours (4 rats/dose/duration of exposure). The quantity of radioactivity absorbed increased with dose and duration of exposure. Percent dermal absorption at 10 hours was 10.32%, 7.07% and 4.51% for doses of 0.08, 0.4 and 3.4 mg/rat respectively. Following a soap and water wash (at 10 hours), 6.46%, 8.06% and 6.13% of the respective doses remained in/on the skin. Percent dermal absorption at 24 hours was 17.58%, 18.43% and 10.88% for doses of 0.08, 0.4 and 3.4 mg/rat respectively. Following a soap and water wash (at 24 hours), 7.91%, 9.50% and 4.97% of the respective doses remained in/on the skin. (MRID 40854603)

k. Other Toxic Endpoints

Bromoxynil is registered for use on transgenic cotton as a contact herbicide to control broadleaf weeds. Non-transgenic cotton is sensitive to bromoxynil. The transgenic variety has been engineered to resist the herbicidal effects of bromoxynil by hydrolyzing nitrile groups to a carboxylic acid, 3, 5 - dibromo-4-hydroxybenzoic acid (DBHA).

The toxicity of DBHA must be considered as a result of the use on transgenic cotton. Significant residues of DBHA are present on transgenic cotton. The Agency has examined the structures of bromoxynil and DBHA. Based on this examination, there was no concern that DBHA would exhibit significant toxicity over that of the parent bromoxynil. Bromoxynil and DBHA are extremely similar in structure, varying only in that bromoxynil has a cyano (-CN) group that has been converted to a carboxyl (-COOH) group in the DBHA metabolite. Conversion to a carboxyl group is generally considered to decrease the toxicity of a molecule. The conversion to the carboxyl group should cause the DBHA to be more polar and therefore more soluble in water and less in fats. Additionally, the presence of the carboxyl group will allow DBHA to combine (conjugate) with certain water soluble molecules (e.g. glucuronic acid) which should further increase DBHA's water solubility and further decrease its solubility in fats. This increased water solubility as well as the decreased fat solubility means that DBHA should be eliminated faster from the organism than bromoxynil, and thus DBHA is less likely than bromoxynil to remain in the cell and engage in the formation of additional, possibly toxic metabolites.

Additional data (four acute studies, two mutagenicity studies, and one subchronic study) addressing the toxicity of DBHA have been submitted to the Agency. These studies are currently

undergoing review. Based on the results of these reviews, if appropriate, the Agency will revise the determination that DBHA has the same toxicity as the parent compound.

l. Toxicity Equivalence

The Agency has determined that bromoxynil (phenol) and bromoxynil octanoate are toxicologically equivalent. Bromoxynil occurs in the form of the phenol (bromoxynil phenol); in the form of the octanoate acid ester of bromoxynil (bromoxynil octanoate); and in the forms of several other organic acid esters of bromoxynil (such as bromoxynil heptanoate, bromoxynil butyrate, etc.). Based on the results of "bridging" studies and other relevant information, bromoxynil (phenol), bromoxynil octanoate and bromoxynil heptanoate have been determined to be toxicologically equivalent on a molar bases.

A critical part of the evidence supporting these conclusions was determination that ester hydrolysis of bromoxynil octanoate to bromoxynil phenol (and octanoic acid) occurs readily and almost completely *in vivo* following oral administration. Later this was shown to be the case for bromoxynil heptanoate.

Since bromoxynil heptanoate and bromoxynil octanoate would be expected to have nearly identical chemical/physical properties (based on their very close chemical structures), it was hypothesized that hydrolysis of bromoxynil heptanoate to bromoxynil phenol (and heptanoic acid) also would occur readily and completely *in vivo* following oral administration. Therefore, using the phenol as the test material would yield the same, both qualitatively and quantitatively, as the results of studies using bromoxynil heptanoate as the test material.

In addition, the Agency required that a general metabolism study and special tissue distribution metabolite study in rats (MRID 431914-01) using bromoxynil heptanoate as the test material be submitted. These studies were received and reviewed. The overall conclusion of the studies was that both bromoxynil heptanoate and bromoxynil octanoate are rapidly and nearly completely converted to bromoxynil phenol *in vivo,* and the pharmacokinetic behavior, metabolism, distribution and excretion of all three compounds are essentially identical in the animal body.

m. Dose-Response Assessment

(1) Determination of Safety for Infants and Children

Under the Food Quality Protection Act (FQPA), P.L. 104-170, which was promulgated in 1996 as an amendment to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA), the Agency was directed to "ensure that there is a reasonable certainty that no harm will result to infants and children" from aggregate exposure to a pesticide chemical residue. The law further states that in the case of threshold effects, for purposes of providing this reasonable certainty of no harm, "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to

take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide residue only if, on the basis of reliable data, such margin will be safe for infants and children."

Under this provision, the Agency will require a tenfold margin of safety if the Agency does not have complete and reliable data to assess pre- or post-natal toxicity relating to infants and children, or if the data indicate pre- or post-natal effects of concern. The data EPA will consider include data submitted in compliance with EPA testing requirements, available data published in the scientific literature, and any other data available to EPA and meeting general scientific standards. Where reproductive and developmental data have been found acceptable by EPA, and the data do not indicate potential pre- or post-natal effects of concern, the tenfold margin of safety can be reduced or removed.

The bromoxynil data submitted to the Agency for review are sufficient for the assessment of hazard to the developing organism (fifth Developmental Toxicity Peer Review Committee memo, 4/21/92). A total of 11 developmental and 3 reproductive toxicity studies were available for review. These include oral prenatal developmental toxicity studies (three in rats, two in rabbits, and one in mice with the phenol; one in rats with the octanoate), dermal prenatal developmental toxicity studies (one each in rats and rabbits with both the phenol and the octanoate), and two dietary two-generation reproduction studies in rats (one with the phenol; one with the octanoate) and one dermal reproduction study. Developmental toxicity was observed, following *in utero* exposure to bromoxynil, in multiple studies, by two routes of exposure, and in three species. The induction of supernumerary ribs was shown to be the most sensitive indicator of developmental toxicity in fetal rats, mice, and (in certain studies) rabbits. Upon consideration of the data base in its entirety, the Agency determined that the developmental NOEL, for the induction of supernumerary ribs, resulting from prenatal exposure to bromoxynil (phenol) is 4 mg/kg/day via the oral route and 10 mg/kg/day via the dermal route. The developmental LOELs for bromoxynil phenol were 5 mg/kg/day by the oral route and 50 mg/kg/day by the dermal route. Other forms of developmental toxicity, including resorptions and malformations, were routinely observed in bromoxynil studies at higher dose levels.

Recently, the Agency reviewed the bromoxynil database for developmental toxicity with particular regard to the requirements of FQPA. It was determined that the FQPA 10x factor should be retained for the sub-population consisting of females 13+. This decision was based upon concerns emanating from the toxicological profile, including evidence of increased susceptibility of fetuses to bromoxynil exposure, the steep dose response curve, and the demonstrated severe developmental effects at doses above the LOEL.

The population of concern is the developing fetus and the endpoint of concern is supernumerary ribs. This endpoint, a developmental anomaly, results from *in utero* exposure; therefore the population subgroup of concern is females 13+ years old. Although some systems in infants and children continue developing, it is unlikely that supernumerary ribs, even though observed across multiple species, would result from postnatal exposure. A 10-fold factor safety factor, as required by FQPA, will provide additional protection for infants and children and ensure a reasonable certainty of no harm to this sensitive subpopulation.

(2) Reference Dose

The Agency has determined that the RfD for bromoxynil is 0.015 mg/kg/day, based on the threshold NOEL/LOEL of 1.5 mg/kg/day determined in a 12-month chronic oral toxicity study in dogs using bromoxynil phenol as the test material. (MRID 40780301, 41304701) Effects observed at the threshold NOEL/LOEL of 1.5 mg/kg/day in the 12-month dog study were slightly decreased body weight gains in males. At the next higher dose level (7.5 mg/kg/day), the following effects were observed in both males and females: decreased body weight gain; increased salivation, panting, liquid feces, and pale gums; decreased erythrocytes, hemoglobin, and packed cell volume; increased urea nitrogen; and increased liver weights. An uncertainty factor of 100 based on interspecies extrapolation (10X) and intraspecies variability (10X) was applied. The 10X safety factor as required by FQPA for the protection of infants and children was removed in establishing the RfD because the endpoint is based on systemic toxicity (decreases in body weight gains) observed in one sex (male) of adult animals (dog) in a long-term (chronic) study (i.e., the endpoint of concern is not a developmental endpoint).

Bromoxynil has not been reviewed by the FAO/WHO Joint Committee.

(3) Carcinogenicity Classification and Risk Quantification

Bromoxynil phenol has been classified by the Agency as a Group C, possible human carcinogen. A low dose extrapolation model (Q_1*) was applied to the experimental animal tumor data for quantification of human risk. For the purpose of estimating carcinogenic risk to humans, the estimated unit risk or Q_1* is 1.03×10^{-1} $(mg/kg/day)^{-1}$. This weight-of-the-evidence determination was based primarily on results in two mouse carcinogenicity studies. In the first study, which used dose levels of 10, 30 and 100 ppm in Swiss albino mice (MRID 00068077), a dose-related increased incidence of liver adenomas/carcinomas combined was observed in the male mice. The increase was statistically significant at 100 ppm. The liver tumor response in male mice included both benign and malignant tumors with the carcinomas contributing to almost one-half of the total adenomas/carcinomas at the mid- and high-dose levels. An increase in the incidence of hyperplastic nodules, some of which may have been adenomas, was also observed in the livers of male mice at the mid- and high-dose levels. An increased incidence of neoplasms was not observed in female mice, but dose levels for the female mice in this study were determined to be too low to assess carcinogenic potential. In the second study, which used dose levels of 20, 75 and 300 ppm in CD-1 mice (MRID 43245501, 43311701), treatment-related increased incidences of liver adenomas, carcinomas and adenomas/carcinomas combined were observed in male mice at all dose levels. For female mice given 300 ppm, slightly increased incidences of liver carcinomas and of adenomas/carcinomas combined also were considered to be related to treatment with bromoxynil phenol. Dose levels in this study were adequate. Information from genotoxicity studies, which included three positive studies, and structure activity relationship (SAR) data provided additional support for the classification.

An increased incidence of neoplasms was not observed in carcinogenicity studies in Fischer 344 rats (MRID 00096521) or in Sprague Dawley rats (MRID 40612501, 41374801). Dose levels in the Fischer 344 rat study, however, were determined to be too low to assess carcinogenic potential.

n. Toxicological Endpoints for Risk Assessment

i. Acute dietary (for females 13+)

For dietary exposure, it is anticipated that the exposure will be to bromoxynil phenol, rather than to bromoxynil octanoate, due to conversion of this ester to bromoxynil phenol in the environment. The NOEL to be used for risk assessment is the developmental toxicity NOEL of 4 mg/kg/day from a developmental toxicity study (MRID 40466802) where bromoxynil phenol was administered to groups of pregnant Sprague-Dawley rats orally by gavage at daily doses on gestation days 6-15, inclusive. The developmental LOEL of 5 mg/kg/day is based on dose-related increases in the incidence of supernumerary ribs observed in the same strain of rats (Sprague-Dawley) in another study (MRID 00116558). The LOEL from another study was used since the LOEL (5 mg/kg/day) in this study was lower than the LOEL (12.5 mg/kg/day) established in the previous study (MRID 40466802).

The 10x safety factor for the protection of infants and children was retained for this population (females 13+) because the endpoint of concern is a develpmental anomaly (supernumerary ribs) occurring following in utero exposure, and thus is relevant for the population of concern (females 13+). Therefore, a MOE of 1000 is required for acute dietary risk assessment for females 13+. This MOE of 1000 includes 10x for inter-species extrapolation, 10x for intra-species variation and 10x for the FQPA safety factor.

ii. Acute Dietary (All populations except females 13+)

The Agency established a NOEL of 8 mg/kg/day from the 13-week range-finding study (MRID 43166701) in which bromoxynil phenol was administered orally in capsules to male and female beagle dogs as the endpoint to be used for acute dietary risk assessment for all populations except females 13+. The LOEL of 12 mg/kg/day was based on increased incidence of panting on day 1, suggestive of a compensatory reaction to the effects of the test material, which at higher doses is expressed as elevated body temperature.

The 10x safety factor for the protection of infants and children was removed for all populations (except females 13+) because the endpoint for acute dietary risk assessment is based on systemic toxicity (increased incidence of panting) in adult dogs. Therefore, a MOE of 100 includes 10x for interspecies extrapolation and 10x for intraspecies variation.

The NOEL of 8 mg/kg/day was selected solely for acute dietary risk assessment based on the recommendations of the Toxicology Endpoint Selection Committee (document dated 5/5/97) which differs from the study NOEL of 1 mg/kg/day (as shown in Table 4, page 11). The reason for establishing a different NOEL is based on finding an endpoint that reflects a single exposure since this time frame was applicable to the acute dietary exposure risk assessment. During the first day of the study, the predominant events were mortality, elevated rectal temperatures and panting. The Toxicology Endpoint Selection Committee considered these 3 events to be directly related to one another. At this dose level (8 mg/kg/day), no deaths and no elevated temperatures were observed. Although some panting was observed during the first week of treatment, it could <u>not</u> be established

that panting occurred after a single dose of the test material on day one. Therefore, a NOEL of 8 mg/kg/day and a LOEL of 12 mg/kg/day (based on panting) were established for the first day of the study.

iii. Short Term (1 to 7 days) and Intermediate Term (1 Week to Several Months) Occupational Exposure

The Agency selected the NOEL of 10 mg a.i./kg/day from the developmental toxicity study (MRID 41163301) in which bromoxynil octanoate (incorporated into Buctril formulation blank) was applied dermally to groups of pregnant Sprague-Dawley rats. A dose-related increased litter incidence of supernumerary ribs was observed at the developmental toxicity LOEL of 15 mg a.i./kg/day. At 20 and 75 mg a.i./kg/day, the litter incidences of supernumerary ribs were increased still further. The maternal toxicity NOEL is 15 mg a.i./kg/day and the maternal toxicity LOEL is 20 mg a.i./kg/day, based on decreased body weight gain and decreased food consumption. (Extracted from "Fifth Developmental and Reproductive Toxicity Peer Review of Bromoxynil", Gary Burin and Ann Clevenger, April 21, 1992). This endpoint is appropriate for all occupational subpopulations because, in this case, it happens to be the most sensitive endpoint overall for estimating occupational risks.

An uncertainty factor of 100, based on interspecies extrapolation (10X) and intraspecies variability (10X) is recommended. An additional 10x is not required because the FQPA safety factor is not applied for occupational exposure scenarios. Therefore, a MOE of 100 is considered appropriate for short term and intermediate term exposure to occupational workers.

iv. Chronic (noncancer) Exposure (dermal route)

The Agency selected the developmental NOEL of 10 mg a.i./kg/day from a developmental toxicity study (MRID 41163301) in which bromoxynil octanoate (incorporated into Buctril formulation blank) was applied dermally to groups of pregnant Sprague-Dawley rats on gestation days 6-15, inclusive. A dose-related increased incidence of supernumerary ribs was observed at the developmental toxicity LOEL of 15 mg a.i./kg/day. At 20 and 75 mg a.i./kg/day, the incidences of supernumerary ribs were increased still further. The maternal toxicity NOEL is 15 mg a.i./kg/day and the maternal toxicity LOEL is 20 mg a.i./kg/day, based on decreased body weight gain and decreased food consumption.

An uncertainty factor of 100, based on interspecies extrapolation (10X) and intraspecies variability (10X) is recommended. An additional 10x is not required because the FQPA safety factor is not applied for occupational exposure scenarios. Therefore, a MOE of 100 is considered appropriate for chronic (non-cancer) term exposure to occupational workers.

v. Inhalation Exposure (Any time period)

Inhalation exposures are expected to be negligible compared to the dermal route. The acute inhalation LC_{50} for bromoxynil octanoate is 0.81 mg/L (M) and 0.79 mg/L (F) (toxicity category III) and the acute inhalation LC_{50} for Buctril formulation is 1.1 mg/liter (toxicity category III). The active

ingredient for all registered end-use products is either bromoxynil octanoate or bromoxynil heptanoate. On this basis, the Agency determined a risk assessment for exposure by the inhalation route is not required.

There are no repeated dose inhalation studies on either bromoxynil octanoate or bromoxynil phenol.

vi. Dermal Absorption

^{14}C-Bromoxynil octanoate, incorporated into the end-use product Buctril, which contained 33.4% Bromoxynil octanoate as the active ingredient, was topically applied to the skin of male Sprague-Dawley rats at doses of 0.08, 0.4 or 3.4 mg/rat for durations of exposure of 0.5, 1, 2, 4, 10 or 24 hours (4 rats/dose/duration of exposure). The quantity of radioactivity absorbed increased with dose and duration of exposure. Percent dermal absorption at 10 hours was 10.32%, 7.07% and 4.51% for doses of 0.08, 0.4 and 3.4 mg/rat respectively. Following a soap and water wash (at 10 hours), 6.46%, 8.06% and 6.13% of the respective doses remained in/on the skin. Percent dermal absorption at 24 hours was 17.58%, 18.43% and 10.88% for doses of 0.08, 0.4 and 3.4 mg/rat respectively. Following a soap and water wash (at 24 hours), 7.91%, 9.50% and 4.97% of the respective dose is assumed for this risk assessment. The occupational cancer risk was determined using the absorption factor of 10% (rounded from 10.32%).

Table 9: Summary of Toxicological Endpoints for Bromoxynil

Exposure Duration	Exposure Route	Endpoint
Acute females 13+	Dietary	Developmental NOEL of 4 mg/kg/day (oral) MRID 40466802 & 00116558 MOE = 1000
Acute general population (except females 13+)	Dietary	Systemic NOEL of 8 mg/kg/day (oral) MRID 43166701 MOE = 100
Chronic (non-cancer)	Dietary	NOEL/LOEL 1.5 mg/kg/day (oral) MRID 40780301 & 41304701 UF= 100 RfD = 0.015 mg/kg/day
Chronic (cancer)	Dietary	Q_1^* = 0.103 (mg/kg/day)$^{-1}$
Short-Term Occupational	Dermal	Developmental NOEL of 10 mg/kg/day (dermal) MRID 41163301 MOE =100
Intermediate-Term Occupational	Dermal	Developmental NOEL of 10 mg/kg/day (dermal) MRID 41163301 MOE=100
Inhalation (any time period)	Inhalation	Not required based on expected lack of exposure
Chronic Occupational (noncancer)	Dermal	Developmental NOEL of 10 mg/kg/day (dermal) MRID 41163301 MOE =100
Carcinogenic Potential Occupational	Dermal	Q_1^* = 0.103 (mg/kg/day)$^{-1}$

2. Exposure Assessment and Risk Assessment

a. Dietary Exposure - Food Sources

i. Directions for Use

There are five bromoxynil end-use products (EPs) with food/feed uses registered to Rhône-Poulenc Corporation. These EPs are presented below.

Table 10: EP Products With Food/Feed Uses

Active Ingredient (code)	EPA Reg No.	Label Acceptance Date	Formulation Class [a]	Product Name
Bromoxynil octanoate (035302)	264-437	6/95	2 lb/gal EC	Buctril® Herbicide
	264-438 [b]	3/95	2 lb/gal EC	Bronate® Herbicide
	264-477 [c]	3/95	1 lb/gal EC	Buctril® + atrazine Herbicide
	264-531 [d]	11/95	4 lb/gal WP[e]	Buctril® Gel
	264-540 [d]	5/95	4 lb/gal EC	Buctril® 4EC Herbicide
Bromoxynil heptanoate (128920)	264-531	11/95	4 lb/gal WP[e]	Buctril® Gel
	264-540	5/95	4 lb/gal EC	Buctril® 4EC Herbicide

[a] The active ingredients for the formulated products are expressed in terms of bromoxynil equivalents.

[b] EPA Reg. No. 264-438 is a MAI formulation that also contains 34.0% isooctyl ester of MCPA (2 lb/gal MCPA equivalents).

[c] EPA Reg. No. 264-477 is a MAI formulation that also contains 21.6% atrazine (2 lb/gal).

[d] EPA Reg. Nos. 264-531 and 264-540 are MAI formulations containing both the octanoic and heptanoic acid esters of bromoxynil for a total of 4 lb bromoxynil equivalent/gal.

[e] This is a gel formulation, designated as a WP.

Based on available data, registered labels should specify the following for rotational crops:

"After applying up to 2 pints/A/season of [Buctril® or Buctril ® 4EC], wait a minimum of 30 days from the date of the application, and then plant any rotational crop."

"After applying more than 2 pints/A/season of [Buctril® or Buctril ® 4EC], only transgenic BXN cotton may be planted as a rotational crop."

[Acceptable studies previously submitted in support of reregistration reflect a maximum seasonal and single application rate of 0.5 lb ai/A, but the use on cotton constitutes a maximum seasonal application rate of 1.5 lb ai/A. Required limited field rotational crop studies reflecting a maximum application rate of 1.5 lb ai/A are on-going.]

The registrant's use directions for corn (field and pop), sorghum, onions and sudangrass are inconsistent and should be amended:

- *Corn (field and pop)*: Use directions on labels 264-437 and 264-531 specify a maximum seasonal rate of 0.5 lb ai/A, while labels 264-477 and 264-540 specify a maximum seasonal rate of 0.75 lb ai/A. In addition, on labels 264-531 and 264-540, maximum seasonal rates listed under "Special Use Directions" (0.75-1.25 lb ai/A) are higher than the maximum seasonal rates listed under "Use Restrictions" (0.5-0.75 lb ai/A). Use directions for corn should be amended so that all labels specify the maximum seasonal use rate of 0.5 lb ai/A, which is supported by available residue data.

- *Sorghum*: Labels 264-437 and 264-531 specify a maximum seasonal rate of 0.5 lb ai/A, while labels 264-477 and 264-540 specify a maximum seasonal rate of 0.75 lb ai/A. In addition, the maximum seasonal rate listed on label 264-540 under "Special Use Directions" (1.25 lb ai/A) is higher than the maximum seasonal rate listed under "Use Restrictions" (0.75 lb ai/A). Labels 264-437 and 264-540 also list maximum single application rates of 0.5-0.75 lb ai/A, but state "do not apply at 0.5 lb ai/A rate to sorghum". Use directions for sorghum should be amended so that all labels specify the maximum single and seasonal use rate of 0.5 lb ai/A, which is supported by available residue data.

- *Onions*: Use directions on labels 264-437 and 264-531 restrict preemergence application to onions grown east of the Mississippi River on muck soils with >10% organic matter. Label 264-540 should be amended to include this restriction. In addition, label 264-437 specifies that postemergence applications should not be made using aerial equipment. This restriction should be deleted from the label since it implies that preemergence applications using aerial equipment are acceptable [under "Application Procedures," the only type of equipment listed for applications on onions is ground equipment].

- *Sudangrass*: Labels 264-437 and 264-531 specify a pre-grazing interval (PGI) of 30 days. The Agency does not currently permit PGIs for grasses grown only for forage. However, since products containing bromoxynil are applied prior to the pre-boot stage, and since the first cutting for forage would occur in approximately 30 days, the Agency will allow the PGI to remain on registered labels.

Refer to Appendix I for a summary of the “Food/Feed Use Patterns Subject to Reregistration for Bromoxynil”.

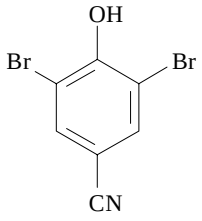
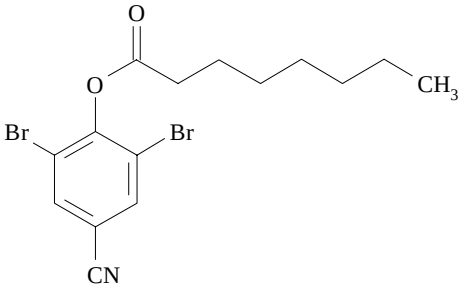
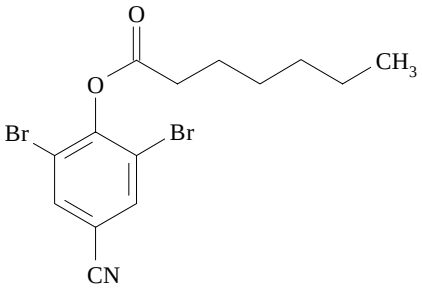
ii. Plant and Livestock Metabolism

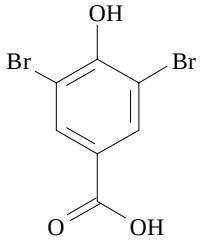
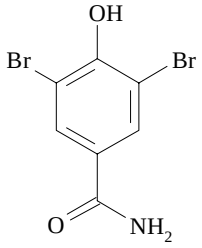
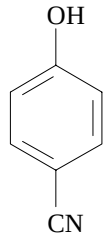
For the purpose of reregistration, the qualitative nature of the residue in plants is adequately understood based on acceptable alfalfa, sweet corn, and transgenic (BXN) cotton metabolism studies conducted using bromoxynil octanoate. The residue of concern in plants other than cotton is bromoxynil *per se*. The residues of concern in transgenic BXN cotton and cotton commodities (i.e. hulls, meal and cotton gin byproducts) are bromoxynil and its metabolite 3,5-dibromo-4-hydroxybenzoic acid (DBHA). The DBHA metabolite is <u>only</u> found in transgenic cotton, and not in other commodities.

The qualitative nature of the residue in livestock is adequately understood for bromoxynil octanoate, based on acceptable ruminant and poultry metabolism studies. Since the metabolite DBHA is found in commodities considered to be livestock feed items, the potential for transfer of secondary residues to livestock exists. The nature of the residue in livestock following oral dosing with DBHA is not adequately understood. The Agency has assumed that DBHA is of potentially equal toxicity to the parent, bromoxynil, and could transfer to livestock tissues in proportion to the parent. Therefore, pending receipt of additional metabolism data for DBHA, EPA has concluded that the residues of concern in livestock are bromoxynil and its metabolite DBHA. Because the registrant has agreed with this Agency assumption and DBHA is included in the tolerance expression for cotton, no additional studies are required.

The structures of bromoxynil, its octanoic and heptanoic acid esters, and its major metabolites are presented in Figure A.

Figure A. Bromoxynil, its octanoic and heptanoic acid esters, and metabolites

Common Name/Chemical Name	
Bromoxynil phenol 3,5-dibromo-4-hydroxybenzonitrile	
Bromoxynil octanoate	
Bromoxynil heptanoate	

Common Name/Chemical Name	
3,5-dibromo-4-hydroxybenzoic acid (DBHA)	
3,5-dibromo-4-hydroxybenzamide	
4-hydroxybenzonitrile	

ii. Residue Analytical Method - Plants and Livestock

Adequate analytical methodology is available for data collection and tolerance enforcement for bromoxynil *per se* in plants. Method I in PAM, Vol. II, is a GLC/MCD that has undergone a successful EPA method validation on wheat grain. This method involves alkaline hydrolysis in methanolic KOH to convert residues to bromoxynil, cleanup by liquid-liquid partitioning, methylation using diazomethane, further cleanup on a Florisil column, and determination by GLC/MCD. Method Ia is the same method, but uses GC/ECD for determination of methylated bromoxynil.

Method A is a GC/MCD or ECD method for the analysis of bromoxynil residues in livestock tissues and is essentially the same as Method I. Method B is a GC/ECD method that is also similar to Method I, with modifications to the cleanup procedures.

Rhône-Poulenc methods SOP 90018 and SOP 90020 and McKenizie Laboratories Method PRM-029 were used in determining residues of bromoxynil for data collection in plants and livestock. These are all GC/ECD methods that are similar to Method I and use modified cleanup procedures following extraction. The limits of quantitation (LOQs) for bromoxynil using these methods are 0.02 ppm for plant commodities and 0.05 ppm for livestock commodities.

The FDA PESTDATA database dated 1/94 (Pam Vol. I, Appendix I) indicates that recovery of bromoxynil octanoate and bromoxynil butyrate using FDA Multiresidue Protocol E (PAM I Section 211.1) is variable. Bromoxynil has recently been tested through Multiresidue Protocols B and C; since bromoxynil was not detected through Protocol C, further testing under Protocol E was not required. Testing under Protocols A and D was not required. This information has been forwarded to FDA for inclusion in the PESTDATA database. No data are reported for the methyl ether of bromoxynil.

For data collection purposes, cottonseed and gin trash samples were analyzed using the analytical method "Bromoxynil: Method of Analysis for Bromoxynil and its Metabolite, 3,5-Dibromo-4-hydroxybenzoic Acid in Cottonseed, Gin Trash, and Seed Processed Fractions using GC-MSD." The method (Method RES9603) has been the subject of an Independent Laboratory Validation (ILV) and an Agency Petition Method Validation (PMV); although there were problems with the LOQ for DBHA in gin trash during the PMV, the Agency concludes the method is adequate for data collection. Additional method validation data submitted to the Agency 1/7/98 address problems encountered with the PMV, and are under review. Approval of the method for enforcement purposes is anticipated.

There is currently no method available for data collection or tolerance enforcement for the DBHA metabolite in livestock commodities. Although the use of measurement of parent bromoxynil residues as a marker for the DBHA metabolite has been discussed, the Agency concluded the use of the parent bromoxynil as a "marker" for the DBHA metabolite in meat, milk, poultry and eggs cannot be supported, based on available residue data for bromoxynil and the DBHA metabolite in cotton gin trash and cottonseed. The registrant has submitted an enforcement method for DBHA. It is currently undergoing Agency review and validation.

iii. Storage Stability

No additional storage stability data are required to support currently registered uses. Bromoxynil octanoate residues are stable in plant commodities stored at -10 C for up to 12 months. Adequate storage stability data have been submitted on the following commodities: alfalfa (forage and hay), barley (grain, forage, hay, and straw), field corn (grain, forage, silage, and fodder), sweet corn (kernels, K+CWHR, cannery waste, and forage), cottonseed, flax (seed and straw), grass (forage, hay, and seed screening), garlic, onion, sorghum (grain, forage, fodder, silage, and hay), and wheat (grain, forage, hay, and straw). Supporting storage stability data for animal matrices are not required since the majority of samples in both the ruminant and poultry feeding studies were analyzed within 21 days of sacrifice.

Adequate data demonstrate stability of bromoxynil phenol in frozen storage in frozen cotton substrates (cottonseed, meal, hulls, gin trash and cottonseed oil) for an interval of at least 9 months. The DBHA metabolite is stable in frozen cottonseed, gin trash, meal, and oil for at least 9 months; in cotton hulls, DBHA residues declined 50% after 1 month of storage.

iv. Magnitude of the Residue/Potable Water - Not Applicable

v. Magnitude of the Residue/Fish - Not Applicable

vi. Magnitude of the Residue/Irrigated Crops - Not Applicable

vii. Magnitude of the Residue /Food Handling - Not Applicable

viii. Magnitude of the Residue/Meat, Milk, Poultry & Eggs

Tolerances are currently established for bromoxynil residues in the fat, meat, and meat by-products of cattle, goats, hogs, horses, and sheep [40 CFR §180.324(a)(1)]. As required based on available data, tolerances are herein established for residues in milk, eggs, and poultry. Acceptable ruminant and poultry feeding studies have been submitted for bromoxynil. No feeding studies conducted using the DBHA metabolite have been submitted; therefore, the results of the bromoxynil feeding studies have been used as the basis for setting tolerances which include the DBHA metabolite. The Agency has recommended inclusion of tolerances for secondary residues in livestock commodities under 40 CFR §180.324(a)(2), i.e. including bromoxynil and DBHA.

Although the Agency previously concluded that residues in poultry commodities could be classified under Category 3 of 40 CFR §180.6(a), i.e., no reasonable expectation of detectable residues, clarification of the Agency's policy with respect to Category 3, changes this conclusion for bromoxynil/poultry. Tolerances are now required for secondary residues of bromoxynil and DBHA in poultry commodities. Tolerances in livestock commodities have been reassessed based on available field trial data and label revisions for livestock feed items, including cotton commodities. The following tolerances for bromoxynil and DBHA residues have been recommended for meat-by-products (mbyp), fat, and meat of cattle, goats, hogs, horses and sheep and in milk, eggs and the meat, fat, and meat by-products of poultry [refer to the "Tolerance Reassessment Summary"]:

<u>Ruminants/Swine</u>

meat	0.5 ppm
mbyp	3.5 ppm
fat	1.0 ppm
milk	0.1 ppm

<u>Poultry</u>

meat	0.05 ppm
fat	0.05 ppm
mbyp	0.3 ppm
eggs	0.05 ppm

A new poultry feeding study had been required, pending submission of additional cotton field trial data. Based on the new field trial data and resultant theoretical maximum dietary burden for poultry, the requirement for a new poultry feeding study is waived.

ix. Magnitude of the Residue/Crop Field Trials Processing Food and Feed

The reregistration data requirements for magnitude of the residue in plants are fulfilled for the following crops: barley, corn (field and pop), flax, garlic, onions, sorghum, wheat, aspirated grain fractions, alfalfa, grasses (including Sudangrass) and mint. Adequate field trial data depicting residues of bromoxynil following applications made according to the maximum or proposed use patterns (provided that changes stipulated under "Directions for Use" are made on registered labels) have been submitted for these commodities. Geographic representation is adequate and a sufficient number of trials reflecting representative formulation classes were conducted. Barley and wheat data can be translated to oats and rye, therefore, residue data are adequate to support the currently registered uses.

The reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled for barley, corn, cottonseed, flaxseed, oats, rye, sorghum, wheat and mint. Data from the barley and wheat processing studies can be translated to oats and rye. Bromoxynil residues do not concentrate in processed plant commodities. Residues of the metabolite DBHA concentrate in cottonseed hulls. No additional data are required.

x. Magnitude of the Residue-Cotton Petition (PP #3F4233)

Reduced rate cotton field trials required by the Agency as a condition of extension of the time-limited tolerances on cotton were submitted to the Agency and found to be adequate for the purpose of tolerance assessment and for dietary risk assessment. Transgenic (BXN) cotton was treated with two broadcast applications of bromoxynil, once at 1 lb ai/A when cotton was 12-14 inches tall, and again at 0.5 lb ai/A at first bloom. The resulting (maximum) seasonal application rate was 1.5 lb ai/A. The Agency has accepted labels specifying: 1 or 2 applications of 0.5 lbs ai/A/application timed prior to planting, just prior to cotton emergence but after weed emergence, or until cotton reaches a height of 12 inches; and a third application at 0.5 lb ai/A after cotton is 12 inches tall during bloom but no later than 75 days prior to harvest. Therefore, the following application instructions to transgenic BXN cotton are required:

> "Apply from just prior to planting cotton until 75 days prior to harvest. Do not exceed 2 applications before cotton is 12 inches tall and 1 application after cotton exceeds 12 inches in height. Make the last application during bloom, but not later than 75 days before harvest."

Based on the new field trial data, revised recommended tolerances for bromoxynil and DBHA residues in cottonseed, cotton gin by-products and cotton hulls are 1.5, 7.0 and 5.0 ppm, respectively [refer to the Tolerance Reassessment Summary].

xi. Reduction of the Residues - Not Applicable

xii. Confined Rotational Crops

Adequate data are available to determine the nature of the residue in rotational crops; the residue of concern in rotational crops is bromoxynil, *per se*.

xiii. Field Rotational Crops

A 30-day plantback interval (PBI) is required for all crops except cotton. Required additional limited field rotational crop studies reflecting a maximum seasonal application rate of 1.5 lb ai/A are ongoing. Acceptable studies previously submitted in support of reregistration reflect a maximum seasonal and single application rate of 0.5 lb ai/A, but the use on cotton constitutes a maximum searsonal application rate of 1.5 lb ai/A.

Submitted field rotational crop data indicate that registered labels should specify the following:

> "After applying up to 2 pints/A/season of [Buctril® or Buctril ® 4EC], wait a minimum of 30 days from the date of the application, and then plant any rotational crop."
>
> "After applying more than 2 pints/A/season of [Buctril® or Buctril ® 4EC], only transgenic BXN cotton may be planted as a rotational crop."

xiv. Anticipated Residues for Dietary Risk Assessment

In spite of a lack of monitoring data for bromoxynil, the anticipated residues summarized below are considered to be highly refined. First, field trial residues in raw agricultural commodities consumed by people were nondetectable; anticipated residues were based on ½ the limit of quantitation (LOQ), and were further refined by percent crop treated data provided by the Agency. Field trial residues from all forages (i.e. sorghum, wheat, oat, corn, alfalfa) and all hays were averaged, and the additional refinement for percent crop treated was applied. Although forages and hays contained detectable bromoxynil residues, the averages used were significantly lower than tolerance-level residues.

Based on evaluation of the additional information provided by the registrant, the Agency reduced the contribution of cotton gin products (gin trash) to the dietary burden for ruminants by assuming it contributes 5% of the diet for beef cattle and 1% for dairy cattle. The refinement for the proposed cotton percent crop treated was also included. The only commodities which contribute significantly to exposure to bromoxynil and/or DBHA in the diet for the general US population (or any subpopulation) are meat, milk, poultry and eggs, based on secondary residues resulting from consumption of livestock feed items.

Tables 10 and 11 summarize anticipated residues (ARs) that were used in the chronic/cancer dietary risk assessment for bromoxynil. The ARs calculated and summarized below were all significantly lower than residues which can be reliably measured using available analytical methods. Table 10 includes ARs for commodities other than cotton and livestock, while Table 11 includes

cotton/livestock ARs for a cotton percent crop treated of 10%. The values for percent crop treated for all commodities were incorporated into the anticipated residues, and were therefore not applied in conducting the DRES analyses.

Table 10: Summary of Bromoxynil Anticipated Residues (Except Cotton/Livestock) for Chronic/Cancer Dietary Risk Assessment

Commodity	Recommended Tolerance (ppm)	Anticipated Residue in RAC (ppm)[1]	% Crop Treated[2]	Anticipated Residue for DRES Run (ppm)
Cereal Grains [wheat, corn, oats, barley, rye, sorghum][3] **Includes processed commodities**	0.05	0.01	10	0.001
Onions	0.1	0.01	62	0.0062
Garlic	0.1	0.01	100	0.01
Peppermint oil/Spearmint oil	--	0.03	71	0.02[4]

[1] Anticipated residues of 0.01 ppm represent ½ the limit of quantitation (LOQ), since there were no detectable residues.

[2] Assuming a maximum percent crop treated of 13% for barley, 10% for corn, 13% for durum wheat, and 10% for spring and other wheats; the likely maximum percent crop treated for remaining cereal grains (i.e. rye, oats, and sorghum) was much lower. For the current dietary risk assessment, 10% crop treated was assumed for all cereal grains as well as for forages/hays.

[3] Since residues do not concentrate in processed commodities of cereal grains, the anticipated residue of 0.001 ppm was used for such commodities in the DRES analysis (i.e. corn oil, flour, etc.).

[4] There is no established tolerance for residues in mint oil. No tolerance is required for residues in mint oil since residues are reduced during processing of hay to produce mint oil; the tolerance for residues in the leaves (0.1 ppm) is adequate to cover residues in the oil.

Table 11: Summary of Bromoxynil Anticipated Residues in Cotton/Livestock for Chronic/Cancer Dietary Risk Assessment

RAC	Tolerance (ppm)	Anticipated residues with Transgenic Cotton Use
Cottonseed	1.5[1]	0.03
Cottonseed meal	--	0.01
Cottonseed oil	--[2]	0.03
Meat[3]	0.5	0.0030
MBYP[3]	3.0	0.0175
Fat[3]	1.0	0.0064
Milk[3]	0.1	0.00040
Swine meat	0.5	0.00016
Swine MBYP	3.0	0.00094
Swine fat	1.0	0.00034
Poultry meat	n/a[4]	0.00025
Poultry MBYP		0.0014
Poultry Skin/Fat		0.00031
Eggs		0.00010

[1] Refer to the 5/13/98 FR notice for details regarding this tolerance in cotton commodities.

[2] The residue level in cottonseed was also used for cottonseed oil in the DRES analysis.

[3] These anticipated residues were also used for meat, fat and meat by-products of horses, goats and sheep in the DRES runs.

[4] Tolerances are not currently established for bromoxynil residues in poultry commodities, but are required based on revised dosing levels in the poultry feeding study (ChemSAC decision dated 10/30/97). Tolerances for poultry commodities are included in the tolerance reassessment.

b. Dietary (food sources) Risk Characterization

The toxicity endpoints identified in the Dose Response Section and the Dietary Exposure Section of this document indicate a chronic, cancer and two acute dietary risk assessments are appropriate for bromoxynil.

i. Acute Dietary Risk (Food Sources)

Previously (9/24/97), a detailed acute dietary exposure analysis was conducted using anticipated residues on blended commodities as applicable and tolerances. Anticipated residues were used for grains, milk and mint oils, without the adjustment for percent crop treated. Tolerance level residues were used for onions; garlic; fat, meat by-products and meat of cattle, goats, hogs, horses and sheep. For bromoxynil, the acute dietary risk from food sources for the general population and all population subgroups, except females 13+ years old did not exceed the Agency's level of concern. The MOE for females 13+ was less than 1000 and therefore exceeded the level of concern.

The registrant has since submitted an acute (probabilistic) dietary analysis including the proposed cotton use incorporating the residue data submitted to support the lower use rates discussed above. The assessment was performed by Novigen Sciences, Inc. for Rhone Poulenc. The assessment used the consumption data from the 1989-1992 Continuing Survey of Food Intakes by Individuals (CSFII). The consumption database used in this probabilistic assessment has been provided to the Agency.

The acute dietary risk assessment was conducted as a probabilistic risk assessment, assuming single day exposure. In the assessment, each person-day of food consumption was matched with randomly selected residue values for this assessment from field trails submitted in support of the chemical. Percent crop treated data were included in the assessment as zeroes to account for portions of the crop to which bromoxynil was not applied. The assessments assumed that 10% of the cotton crop would be treated. This process was repeated one thousand times for each person-day in the consumption database. The assessment assumed that the treated commodities were evenly distributed in the food supply. Secondary residues in meat and milk from consumption of treated feed items were included in the form of a probabilistic assessment, varying residues in the diet in accordance with the data from the field trails. The assumptions for the dietary exposure were reviewed and found to be acceptable.

The acute assessment used a NOEL of 4 mg/kg BW/day based on developmental effects for females 13+ years old and a NOEL of 8 mg/kg BW/day based on systemic effects for all populations except females 13+ years old. For the acute assessment, all of the subgroups evaluated have MOEs far in excess of the required value of 1000 for females 13+ and 100 for all populations except females 13+ years old indicating that the potential for an adverse effect from a single day dietary (food only) exposure is unlikely. The MOE is a measure of how closely the exposure comes to the NOEL and is calculated as a ratio of the NOEL to the exposure (NOEL/exposure). The MOEs and the exposure values for various population subgroups are listed in Table 12 below.

Table 12: Acute Dietary Assessment for Bromoxynil

Population Subgroup	Exposure (mg/kg BW/day)	MOE
US population	0.000137	>58,000
Non-Nursing Infants	0.000244	>32,000
Nursing Infants	0.000097	> 82,000
All Infants	0.000219	> 36,000
Children (1-6 years)	0.000288	>35,000
Children (7-12 years)	0.000144	>55,000
Females 13+	0.000082	>24,000

ii. Chronic Dietary Risk (Food Sources)

Previously (9/24/97), the chronic and carcinogenic dietary exposure analysis from food sources (including cotton) were conducted using refined residue levels based on anticipated residues and percent crop treated information. A revised chronic and carcinogenic dietary exposure analysis from food sources (including cotton) has been conducted for bromoxynil in conjunction with Rhône-Poulenc's 9/24/97 petition to increase the acreage for application to transgenic BXN cotton. [This petition was granted, 5/13/98. Cotton acreage permitted for bromoxynil application increased from 400,000 acres to 1.3 million acres.] The current assessment has been prepared using new cotton residue data submitted by Rhône-Poulenc along with other data supporting re-instatement of the time-limited tolerances for bromoxynil and its metabolite DBHA (3,5-dibromo-4-hydroxybenzoic acid) in cotton commodities.

Table 13 below lists the results of the chronic dietary risk analysis conducted based on the new residue data, and on revised anticipated residues which incorporate all uses of bromoxynil (refer to Tables 10 & 11 above).

Table 13: Chronic Dietary Risk for Bromoxynil - % of RfD

Population Subgroup	Registered Uses (i.e., Excluding Cotton)	Cotton @ 10 %CT + Registered Uses
U.S. Population	<1	<1
Non-Nursing Infants[1] (<1 Year Old)	<1	<1

[1]Non-Nursing Infants is the population subgroup with the highest exposure to bromoxynil.

For chronic effects other than cancer, for all population subgroups, less than 1% of the RfD was consumed.

Table 14 below shows the results of the carcinogenic dietary risk analyses conducted based on the new residue data, and on revised anticipated residues which incorporate all uses of bromoxynil (refer to Tables 10 & 11 above).

Table 14: Carcinogenic Dietary Risk for Bromoxynil

Commodity	Registered Uses (i.e., Excluding Cotton)	Cotton @ 10 %CT + Registered Uses
Grain/cottonseed	2.0×10^{-7}	2.6×10^{-7}
Bulb vegetables	0.7×10^{-7}	0.7×10^{-7}
Meat	3.5×10^{-7}	7.0×10^{-7}
Milk	4.0×10^{-7}	4.4×10^{-7}
Poultry	$<0.1 \times 10^{-7}$	0.2×10^{-7}
Total Dietary Risk	**1.0×10^{-6}**	**1.5×10^{-6}**

These risk estimates are based on anticipated residues and percent crop treated information which represents the most refined estimate the Agency can currently conduct. The additional (0.5 in 1 million) risk resulting from the cotton use is due to high residue levels of the metabolite, DBHA. DBHA is formed by the transgenic BXN cotton which has been engineered to hydrolyze the nitrile group of bromoxynil to a carboxylic acid, DBHA. DBHA is currently considered toxicologically equal to bromoxynil.

c. Dietary Exposure - Drinking Water

The Office of Pesticide Programs is in the process of developing procedures and methods for determining the likelihood of a pesticide occurring in drinking water and, if so, the exposure levels and associated risk. Previous exposure and risk assessments have been conducted for bromoxynil as a possible contaminant in drinking water. The following estimation of exposure and risk from drinking water reflects the latest information and methods for estimating drinking water exposure.

i. Ground Water

Bromoxynil octanoate does not exhibit the mobility or persistence characteristics of pesticides that are normally found in ground water. Bromoxynil phenol (which bromoxynil octanoate readily degrades to) has the potential to leach to ground water under certain conditions, however, it rapidly degrades under aerobic and anaerobic conditions reducing the likelihood of ground water contamination. Limited monitoring information for bromoxynil in ground water is available. The "Pesticides in Ground Water Database" (EPA 1992) reports sampling for bromoxynil in 107 wells in four counties in Oregon between 1985 and 1987. The well samples in each area (public water supply and domestic) were selected based on suspected vulnerability, susceptibility to contamination, and availability of information on well construction and depth. No additional information on the details of the monitoring was available. No detections of bromoxynil were reported.

Additional monitoring data from the United States Geological Survey (USGS) National Water Quality Program (NAQWA) represent the highest quality data and most recent data available (1993-1994). The program was carefully designed to obtain monitoring data for surface and ground waters from diffuse (non-point) sources. For ground water, one detection of bromoxynil (concentration not specified) was reported from a total of 2, 245 samples. Clearly, these compounds (bromoxynil phenol and octanoate) are not considered candidates for restricted use due to ground water concerns and the potential for ground water contamination (and exposure) from bromoxynil is extremely low.

DBHA, a cotton metabolite, is not expected to be found in ground water.

ii. Surface Water

Environmental fate studies indicate that bromoxynil (phenol and octanoate) should not persist in surface waters, although water monitoring data from the USGS NAWQA program show that bromoxynil has been detected in 1.1% of surface water samples. Modeled estimated environmental concentrations (EECs) were based on the cotton use and not the small grains, corn or other uses of bromoxynil because, it has been the Agency's experience, that using cotton as opposed to these crops results in a higher estimated surface water exposure. Cotton represents the most conservative use for surface water exposure (i.e. the highest possible exposure scenario).

A Tier II analysis based on the PRZM - EXAMS model (Pesticide Root Zone Model Version 2.3 plus Exposure Analysis Modeling System Version 2.94) was conducted for the cotton use. PRZM-EXAMS uses data on the physical-chemical properties of the pesticide plus soil and topographic characteristics, weather data, and water quality parameters for the modeled site. The model uses this information to estimate runoff from a 10 hectare agricultural field into an immediately adjacent 1 hectare by 2 meter deep pond. PRZM-EXAMS considers reduction in dissolved pesticide concentrations due to adsorption of pesticide to soil or sediment, incorporation, degradation in soil before wash off to a water body, direct deposition of spray drift into the water body, and degradation of the pesticide within the water body.

Water monitoring data from the U.S. Geological Survey (USGS) NAWQA Program were reported during the 1993-1995 period from 7 of 20 river basins throughout the U.S. The NAWQA Program examined drainage basins that were primarily agricultural use. The percentage of detections was 1.1% from a total of 1,925 surface water samples. Analysis of the 20 detections $\geq$0.03 ppb yielded a median value of 0.105 ppb with a mean of 0.53 ppb. The maximum concentration was one data point at 6.1 ppb (12.2 ppb when accounting for 50% recovery) measured in the South Platte River Study Unit, CO. For urban land use, bromoxynil was not detected in surface waters. It is important to note the laboratory recoveries were approximately 50%. Apparently the laboratory recoveries did not vary considerably from the 50% level.

Based on model estimates (using PRZM-EXAMS), the maximum or peak estimated concentration for bromoxynil was 12.3 parts per billion (ppb) and the maximum estimated long-term mean was 0.24 ppb (using 36 years of weather data). These values represent what might be expected in a small water body near a cotton field highly prone to runoff. The maximum peak estimated concentration for bromoxynil from the model correlates with the highest value detected in the USGS monitoring data, when this measured value is been corrected for an analytical recovery rate of 50%.

To estimate a reasonable high end exposure for the human health risk assessment, EPA focused on the calculated time weighted annual mean concentrations of bromoxynil at each of 11 USGS monitoring sites, which the EPA views as located in watersheds likely to have bromoxynil use. (These values were not corrected for the analytical recovery rate of 50%.) These time weighted annual mean concentrations ranged from 0.011 ppb to 0.18 ppb, with 10 out of the 11 sites with time weighted annual mean concentrations below 0.05 ppb. Six of the 10 sites had time weighted annual mean concentrations at or below 0.014 ppb. The highest annual time-weighted mean (0.18 ppb) was

located in a relatively small watershed (approximately 100 square miles) in a relatively small water body, and the calculated annual mean value at this site was significantly influenced by the presence of a single high value (the highest value found in all of the available monitoring data). Based on this information, EPA believes that 0.05 ppb is a reasonable high end estimate for purposes of estimating drinking water exposure. However, because available monitoring data are variable, EPA has imposed surface water monitoring requirements as a condition of the cotton registration. These data are important to improve EPA's understanding of the potential human exposure to bromoxynil in drinking water.

Table 15: Bromoxynil Exposure Values Estimated for Surface Water Sources of Drinking Water

Subpopulation by weight, water consumption per day	Acute (mg/kg/day)[1]	Chronic (mg/kg/day)[1]
Male 70 kg, 2 Liters	3.5×10^{-4}	1.4×10^{-6}
Female 60 kg, 2 Liters	3.5×10^{-4}	1.6×10^{-6}
Child 10 kg, 1 Liter	12×10^{-4}	5×10^{-6}

[1] Exposure (mg/kg/day) = $\frac{\text{(concentration in water ug/L) (0.001 mg/ug) (water consumption L/day)}}{\text{(body weight kg)}}$.

Where the 4-day (acute) exposure concentration is 12.2 ppb and the reasonable high end estimate for purposes of estimating drinking water exposure (chronic) is 0.05 ppb.

iii. Dietary Risk Characterization - Drinking Water

The potential for ground water contamination (and exposure) from bromoxynil is extremely low. Environmental fate studies indicate that bromoxynil (phenol and octanoate) should not persist in surface waters. Estimates of exposure were based on surface water estimates for the cotton use which, considering all of the uses of bromoxynil, represents the most conservative scenario for drinking water exposure. The exposures and risks are summarized in Table 16 below.

Table 16: Bromoxynil Exposure and Risk from Drinking Water

Subpopulation by weight, water consumption/ day	Drinking water Exposure (mg/kg/day)[1]		Risk from Drinking Water		
	Acute	Chronic	Acute[1] MOE	Chronic[2]	Cancer[3]
Male 70 kg, 2 Liters	3.5×10^{-4}	1.4×10^{-6}	>10,000	< 1%	0.2×10^{-6}
Female 60 kg, 2 Liters	3.5×10^{-4}	1.6×10^{-6}	>10,000	<1 %	
Child 10 kg, 1 Liter	12×10^{-4}	5×10^{-6}	>10,000	<1 %	N/A*

[1] Acute Risk = MOE = NOEL (mg/kg/day) / Exposure (mg/kg/day). The NOEL for females ages 13+ is 4 mg/kg/day and for the other subpopulation groups is 8 mg/kg/day (for details see Dose Response Section of document). A MOE of greater than 1000 is recommended for females 13+ and greater than 100 for all other populations except females. To estimate acute exposure, a value of 12.2 ppb, derived from monitoring data and closely matched with modeling estimates, was used. The drinking water chronic exposure (0.05 ppb) was estimated using a reasonable high end estimate from monitoring data.

[2] %RfD = Chronic Dietary Risk = Exposure as a percentage of the RfD (0.015 mg/kg/day). The %RfD is considered a risk concern when it exceeds 100%.

[3] The upper bound Carcinogenic Risk = risk quotient Q_1^* ($0.103\ [\text{mg/kg/day}]^{-1}$) X Chronic Exposure ($1.4 \times 10^{-6}$ mg/kg/day). The chronic exposure value is based on a 0.05 ppb concentration of bromoxynil in drinking water.

* N/A = Not Applicable. Cancer Risk has only been estimated for the general population (in this case the average exposure between males and females) and is based on a 70 year lifetime.

There appears to be no chronic or acute risk of concern for any subpopulations from drinking water (only) when using monitoring data or modeling data for the acute exposure and risk and when using monitoring data for the chronic and cancer exposure and risk.

The USGS monitoring data indicate that exposure is possible on a seasonal basis, but rare considering there was one significant concentration out of 1,925 samples (and only 20 detects total). These data showed that approximately one percent of the samples were positive for bromoxynil. Most importantly, the sampling was conducted predominantly in locations not representative of drinking water intakes, and none of the samples were from "the tap".

d. Aggregate Risk

Aggregate risk is estimated by combining dietary (food and water) and residential exposures. Bromoxynil has no residential uses, therefore, the aggregate risk estimate will be based on the dietary exposure from food and water only, for the most highly exposed population subgroups and the general population as appropriate. Table 23 (below) shows the aggregate risk for bromoxynil; however, for details concerning the exposure to determine these estimated aggregate risks, see Tables 12-16. Details concerning the assumptions and risk characterizations have been previously discussed and are in the corresponding sections of the document.

Table 17: Estimates of Aggregate Risk from Bromoxynil from Dietary Sources (Food and Water) including the use on BXN Transgenic Cotton

Population Subgroup[1]	Chronic %RfD[2] %CT + Registered Uses	Acute MOE[3] %CT + Registered Uses	Cancer[4] %CT + Registered Uses
whole U.S. population	<1%	>16,000	1.7×10^{-6}**
females 13+	<1%	> 11,000	N/A*
children 1-6 years	<1%	>5,000	N/A*

[1] The most highly exposed population subgroups.

[2] Chronic risk is a concern when more than 100% of the RfD is consumed.

[3] An MOE >1000 indicates there is no aggregate acute dietary risk concern for females 13+. For the other subpopulations, an MOE of >100 indicates there is no aggregate acute dietary risk concern.

$$MOE_{acute} = \frac{NOEL}{\text{Aggregate exposure (food + water)}}$$

[4] As discussed in Table 16 the carcinogenic risk from drinking water is 0.2×10^{-6}.

* N/A = Not Applicable. Cancer Risk has only been estimated for the general population (in this case the average exposure between males and females) because it is based on a 70 year lifetime.

** The aggregate risk is based on risk from food plus the drinking water risk (0.2×10^{-6}).

The chronic and acute aggregate risk estimates do not trigger a concern. The dietary (food) exposure and risk is highly refined using anticipated residues and considering percent crop treated information resulting in a highly refined cancer risk estimate. The estimated chronic drinking water risk (from surface water sources) was based on a reasonable high end estimate of exposure, based on limited monitoring data, and is potentially much lower since the level of bromoxynil may only occasionally occur in water and fate data indicate that it degrades in approximately 7 days.

Because of FQPA aggregate and cumulative risk considerations, it is important to note that bromoxynil heptanoate (which is not part of the reregistration case) has some of the same uses as bromoxynil phenol and octanoate, but not all of the same uses and no additional ones. Therefore, the exposure and risk associated with the use of the heptanoate is not greater than that described for the phenol and octanoate. Also, the heptanoate would not “add” to the current risk described above since these active ingredients would be used “in place” of one another rather than in an “additive” manner. Therefore, the exposure and risk estimates presented here for the bromoxynil phenol and octanoate would present the same or more conservative risk estimate for the heptanoate and, it would not be appropriate to add them together for the purposes of aggregate risk.

e. Cummulative Risk

Section 408(b)(2)(D)(V) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodology to fully resolve the scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further, through examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides for which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and any pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

In the case of bromoxynil, EPA has not conducted a detailed review of common mechanism yet to determine whether it is appropriate, or how, to include this chemical in a cumulative risk assessment. After EPA develops a methodology to apply common mechanism of toxicity issues to risk assessments, the Agency will develop a process (either as part of the periodic review of pesticides or otherwise) to reexamine these tolerance decisions.

3. Occupational Exposure and Risk Characterization

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete.

The toxicological endpoints of concern for occupational exposure are summarized in the Dose Response Section. It should be noted for short term and intermediate term exposure the toxicological endpoint is from a dermal developmental study. Therefore, a separate dermal absorption factor was not applied. The cancer risk was determined using an oral toxicity endpoint which, for occupational risk, necessitates the use of a dermal absorption factor. The dermal absorption for the bromoxynil octanoate is 10.32% and the bromoxynil phenol is 1.92% based on studies (MRIDs 40854602 & 40854603) summarized in the Hazard Assessment Section of this document. For the sake of simplicity and to remain consistent, the occupational cancer risk was determined using an absorption factor of 10% (rounded from 10.32%). Lastly, although a chronic (noncancer) endpoint was identified for bromoxynil, a chronic-term exposure/risk assessment was not conducted. Because it is unlikely that there will be chronic exposures to bromoxynil a chronic risk assessment is not warranted. Inhalation exposures were considered negligible compared to the dermal route and no inhalation endpoint was identified for use in risk assessment.

a. Handler Exposures and Risk

i. Handler Exposures and Assumptions

EPA has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual use patterns associated with bromoxynil. Based on the use patterns, seven major exposure scenarios were identified for bromoxynil:

(1) mixing/loading liquids for groundboom applications;
(2) mixing/loading liquids for aerial and sprinkler irrigation applications;
(3) groundboom applications;
(4) aerial applications;
(5) flaggers;
(6) mixing/loading/applying liquid formulations by groundboom; and
(7) mixing/loading/applying liquid formulations by aircraft.

Bromoxynil is also packaged in water soluble gel packets. No exposure data are available for the water soluble gel packets, but the exposure potential is expected to be less than for open pouring of liquids, which is included in the risk assessment. Inhalation exposures are expected to be negligible compared to the dermal route. The acute inhalation LC_{50} for bromoxynil octanoate is 0.81 mg/L (M) and 0.79 mg/L (F) (toxicity category III) and the acute inhalation LC_{50} for the Buctril formulation is 1.1 mg/liter (toxicity category III). On this basis, the Agency determined a risk assessment for exposure by the inhalation route is not required.

A chemical specific exposure study (MRID 41730001) was reviewed and accepted by EPA in 1991. However, EPA has concerns regarding the low field recoveries reported in the study. For

example, the field recoveries fortified with the formulated product and analytical grade for the handwash averaged 56 percent with a coefficient of variation (c.v.) of 48 percent; facial wipes averaged 56 percent with a c.v. of 64 percent; and the whole-body dosimeters averaged 53 percent with a c.v. of 55 percent. The Agency's concern is that the low field recoveries (especially at low fortification levels) may have produced exposure values that are "false negatives". Therefore, and in order to provide a criterion for comparison with the Pesticide Handlers Exposure Database (PHED) data, the Agency characterizes the data as "low to medium grade" quality data. The PHED based data are considered "medium to high grade" quality data. Because of the quality of the chemical-specific study (MRID 41730001), the risk assessment in this document is based on PHED V1.1 data.

PHED V1.1 surrogate data were used to estimate exposures for handlers wearing "baseline," "PPE," and "engineering controls." The baseline represents: long sleeved shirts, long pants and no gloves, and using open mixing/loading and open cab tractors. PPE is based on handlers wearing coveralls over long sleeved shirts, long pants and chemical resistant gloves while using open mixing/loading and open cab tractors. The engineering controls are based on long sleeved shirts, long pants, and no gloves (except where noted) while using closed loading systems and enclosed cockpits/tractors.

When evaluating the exposure and risk estimates presented in this document the following should be taken into consideration:

- The PHED estimates do not account for the potential exposure reduction from the "wide-mouth" containers designed to reduce splashing during pouring (2.5 gallon containers) used in the chemical specific study, and therefore, potentially overestimate risks to bromoxynil.

- Data indicate that most private applicators do their own mixing and loading for groundboom applications. The registrant indicated that approximately 95% of bromoxynil is mixed and loaded by the same person who applies the pesticide. Therefore, these combined exposures are included in the risk assessment.

- It is reasonable to assume that for aerial and commercial groundboom applications the mixer/loader and the applicator are separate handlers. Aerial and commercial groundboom applications are limited. Apparently aerial applications to range land, sod and turfgrass seed farms seldom occur, if ever.

The exposure assessments using PHED V1.1 surrogate data are presented in Table 18. Table 19 summarizes the caveats and parameters specific to each exposure scenario and corresponding risk assessments.

The daily dose was calculated using the following formula:

$$\text{Daily Dose}\left(\frac{mg}{Kg\ Day}\right) = \text{Daily Exposure}\left(\frac{mg}{Day}\right) \cdot \left(\frac{1}{\text{Body Weight (Kg)}}\right) \cdot \%\ \text{dermal absorption}$$

Table 18: Short-term and Intermediate-term Dermal Exposure to Bromoxynil

Exposure Scenario	Dermal Unit Exposure (mg/lb ai)			Crop Type[d]	Acres Treated/Day[e]	Maximum Application Rate (lb ai/acre)[f]	Daily Dermal Dose (mg/kg/day)[g]		
	Baseline[a]	PPE[b]	Engineering Controls[c]				Baseline	PPE	Engineering Controls
MIXER/LOADER									
Mixing/Loading Liquids for Groundboom Application	2.9	0.023	0.0086 (gloves)	Wheat	240	0.5	5.8	0.046	0.017
				Corn	150		3.6	0.029	0.011
				Cotton	200		4.8	0.038	0.014
				Garlic	69		1.7	0.013	NA
				Onions	77		1.9	0.015	0.0055
				Seedling Alfalfa-East	50		1.2	0.0096	NA
				Seedling Alfalfa-West	133		3.2	0.025	0.0095
				Canary Grass	50		1.2	0.0096	NA
				Oats and Rye	50		1.2	0.0096	NA
				Barley	133		3.2	0.025	0.0095
				Mint	48		1.2	0.0092	NA
				Sorghum	200		4.8	0.038	0.014
				Flax	70		1.7	0.013	NA
				Turfgrass Seed Farm	111		2.7	0.021	0.0080
				Sod Farm	100		2.4	0.019	0.0072
				Range Land	250		6.0	0.048	0.018
Mixing Liquids for Sprinkler Irrigation and Aerial Applications				All	350		8.5	0.067	0.025
APPLICATOR									
Groundboom Applicator	0.015	0.011	0.0050	Wheat	240	0.5	0.03	0.022	0.010
				Corn	150		0.019	0.014	0.0063
				Cotton	200		0.025	0.018	0.0083
				Garlic	69		0.0086	0.0063	NA
				Onions	77		0.0096	0.0071	NA
				Seedling Alfalfa-East	50		0.0063	0.0046	NA
				Seedling Alfalfa-West	133		0.017	0.012	0.0055
				Canary Grass	50		0.0063	0.0046	NA
				Oats and Rye	50		0.0063	0.0046	NA
				Barley	133		0.017	0.012	0.0055
				Mint	48		0.006	0.0044	NA
				Sorghum	200		0.025	0.018	0.0083

Table 18: Short-term and Intermediate-term Dermal Exposure to Bromoxynil

Exposure Scenario	Dermal Unit Exposure (mg/lb ai)			Crop Type[d]	Acres Treated/Day[e]	Maximum Application Rate (lb ai/acre)[f]	Daily Dermal Dose (mg/kg/day)[g]		
	Baseline[a]	PPE[b]	Engineering Controls[c]				Baseline	PPE	Engineering Controls
Groundboom Applicator	0.015	0.011	0.0050	Flax	70		0.0088	0.0064	NA
				Turfgrass Seed Farm	111		0.014	0.010	NA
				Sod Farm	100		0.013	0.0092	NA
				Range Land	250		0.031	0.023	0.010
Aerial Application - Enclosed Cockpit	No Data	No Data	0.005	All	350		No Data	No Data	0.032
FLAGGERS									
Flagging Liquids	0.011	0.01	0.00022	All	350	0.5	0.032	0.029	0.00064
MIXER/LOADER/APPLICATOR[h]									
Mixing/Loading Liquids and Applying with Groundboom Equipment	2.9	0.037	0.014	Wheat	240	0.5	5.8	0.074	0.028
				Corn	150		3.6	0.046	0.018
				Cotton	200		4.8	0.062	0.023
				Garlic	69		1.7	0.021	0.0081
				Onions	77		1.9	0.024	0.0090
				Seedling Alfalfa-East	50		1.2	0.015	0.0058
				Seedling Alfalfa-West	133		3.2	0.041	0.016
				Canary Grass	50		1.2	0.015	0.0058
				Oats and Rye	50		1.2	0.015	0.0058
				Barley	133		3.2	0.041	0.016
				Mint	48		1.2	0.015	0.0056
				Sorghum	200		4.8	0.062	0.023
				Flax	70		1.7	0.022	0.0082
				Turfgrass Seed Farm	111		2.7	0.034	0.013
				Sod Farm	100		2.4	0.031	0.012
				Range Land	250		6.0	0.077	0.029

a PHED V1.1; Baseline: handlers wearing long sleeved shirts, long pants and no gloves while using open mixing/loading and open cab tractors.

b PHED V1.1; PPE: handlers wearing long sleeved shirts, long pants and chemical resistant gloves (no gloves for applicators) while using open mixing/loading and open cab tractors; flaggers wearing coveralls over long pants, long sleeved shirts, and no gloves

c PHED V1.1; Engineering Controls: long pants, long sleeved shirt, chemical resistant gloves for closed mixing/loading; long pants, long sleeved shirt, no gloves for enclosed cab tractor (groundboom) and inside truck (flagger); and aerial applicators wearing long pants, long sleeved shirts, and no gloves while using enclosed cockpit fixed wing airplanes (open cockpit data are not available).

d,e Crop and acres. Sources: (1) Evaluation of Bromoxynil Worker Exposure Study; Memorandum from C. Lunchick to P. Parsons dated April 29, 1991. (2) Bromoxynil Heptanoate and Bromoxynil Octanoate, May 1996. Use data for Bromoxynil Exposure Analysis; Memorandum from G.W. Keitt, PhD to S.Bachus dated 7/15/92.

f Application rates are from maximum values found in the following bromoxynil labels: 264-477, 264-438, 264-531, 264-540, and 51036-256.

g Daily Dermal Dose (mg/kg/day) = [Exposure (mg/lb ai) * Appl. Rate (lb ai/A) * Acres Treated]/60 kg body weight. Short-term and intermediate-term toxicological endpoint is from a dermal study; therefore, adjustment for dermal absorption is not necessary.

h Mixer/Loader estimates + Applicator estimates.

Table 19: Exposure Scenario Descriptions for Uses of Bromoxynil

Exposure Scenario	Data Source	Standard Assumptions	Comments[a]
Mixer/Loader Exposure			
Mixing/Loading Liquids	PHED V1.1	**Baseline:** PHED V1.1, handlers wearing long sleeved shirts and long pants; open mixing/loading	**Baseline:** "Best Available" grades: Dermal and hands acceptable grades. Dermal = 72 to 122 replicates; Hands = 53 replicates. High confidence in dermal data. No protection factors (PFs) were necessary.
		PPE: MOE Assessment: PHED V1.1; handlers wearing long sleeved shirts, long pants, and chemical resistant gloves; open mixing/loading. Cancer Assessment: PHED V1.1; handlers wearing long sleeved shirts, long pants and chemical resistant gloves; open mixing/loading	**PPE:** "Best Available" grades: Hands and dermal acceptable grades. Hands = 59 replicates; Dermal = 72 to 122 replicates. High confidence in dermal data. No PFs were necessary.
		Engineering Controls: PHED V1.1; handlers wearing long sleeved shirts and chemical resistant gloves; closed mixing/ loading	**Engineering Controls:** "Best Available" grades: Dermal and hands acceptable grades. Dermal = 16 to 22 replicates; Hands = 31 replicates. High confidence in dermal data. No PFs were necessary.
Applicator Exposure3			
Groundboom Tractor	PHED V1.1	**Baseline:** PHED V1.1; handlers wearing long sleeved shirts and long pants	**Baseline:** "Best Available" grades: Dermal and hands acceptable grades. Dermal = 23 to 42 replicates; Hands = 29 replicates. High confidence in dermal data.
		PPE: MOE Assessment: PHED V1.1; handlers wearing coveralls over long sleeved shirts, long pants, and chemical resistant gloves; open mixing/loading. Cancer Assessment: PHED V1.1; handlers wearing long sleeved shirts, long pants and chemical resistant gloves; open cab tractors	**PPE:** "Best Available" grades: Hands grades A,B,C; dermal acceptable grades. Hands = 21 replicates; Dermal = 23 to 42 replicates. Medium confidence in dermal data. No PFs were necessary for the cancer assessment, 50 percent PF used to simulate coveralls for MOE assessments.
		Engineering Controls: PHED V1.1; handlers wearing long pants, long sleeved shirts, and no gloves; enclosed tractor cab	**Engineering Controls:** "Best Available" grades: Dermal and Hands = grades A,B,C,. Dermal = 20 to 31 replicates; Hands = 16 replicates. Medium confidence in data. No PFs were necessary.
Aerial Application - Enclosed Cab	PHED V1.1	**Engineering Controls:** PHED V1.1; applicators wearing long pants, long sleeved shirts and no gloves while using enclosed cockpit fixed wing airplanes (open cockpit data are not available)	**Engineering Controls:** "Best Available" grades: Dermal = grades A,B,C; hands = acceptable grades. Dermal = 24 to 48 replicates; hands = 34 replicates. Medium confidence in dermal data. No PFs were necessary.

Table 19: Exposure Scenario Descriptions for Uses of Bromoxynil

Exposure Scenario	Data Source	Standard Assumptions	Comments[a]
Flagger Exposure			
Flagging Liquids	PHED V1.1	**Baseline:** PHED V1.1; flaggers wearing long pants, long sleeved shirts, and no gloves	**Baseline:** "Best Available" grades: hands and dermal = acceptable grades. Dermal = 16 to 18 replicates; hands = 16 replicates. High confidence in dermal data. PHED data were used for baseline, no PFs were necessary.
		PPE: PHED V1.1; flaggers wearing coveralls over long pants, long sleeved shirts, and no gloves	**PPE:** The PPE scenario was calculated by using a 50 percent PF for the addition of coveralls.
		Engineering Controls: PHED V1.1; flaggers wearing long pants, long sleeved shirts, and no gloves; inside enclosed truck cab	**Engineering Controls:** Calculated by applying a 98 percent PF to the baseline assessment.

[a] "Best Available" grades are defined by OREB SOP for meeting Subdivision U Guidelines. Best available grades are assigned as follows: matrices with grades A and B data and a minimum of 15 replicates; if not available, then grades A, B, and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality and number of replicates. Data confidence are assigned as follows:

High = grades A and B and 15 or more replicates per body part
Medium = grades A, B, and C and 15 or more replicates per body part
Low = grades A, B, C, D, and E or any combination of grades with less than 15 replicates

ii. Handler Risks

The short-term and intermediate-term MOEs were calculated using the following formula:

$$MOE = \frac{NOEL\left(\frac{mg}{kg\ day}\right)}{Daily\ Dose\left(\frac{mg}{kg\ day}\right)}$$

For the short-term and intermediate-term risk assessment, a NOEL of 10 mg/kg/day from a dermal study was used along with a 60 kg body weight (the standard assumption for the weight of a women) since the toxicological endpoint is for developmental effects.

The lifetime average daily dose (LADD), used to calculate the cancer risk, was calculated using the following formula:

$$\text{LADD (mg/kg/day)} = \left[\frac{\text{Daily Dose (mg/kg/day)} * \text{Treatments Per Year}}{\text{365 Days Per Year}}\right] * \left[\frac{\text{40 Work Years}}{\text{75 Lifetime Years}}\right]$$

The cancer risks were calculated using the following formula:

$$\text{Cancer Risk} = \text{LADD (mg/kg/day)} * Q_1^{*} (\text{mg/kg/day})^{-1}$$

Table 20 presents the corresponding MOE estimates for the short-term and intermediate-term exposures. Table 21 presents the cancer risk assessment for private handlers, which includes combined mixer, loader and applicator risks. Table 22 presents the cancer risk assessments for commercial handlers, for whom the mixer/loader is assumed to be different than the applicator.

Table 20: Short-term and Intermediate-term Risks of Bromoxynil

Exposure Scenario	Crop Type	Dermal MOE[a]		
		Baseline[b]	PPE[c]	Engineering Controls[d]
MIXER/LOADER				
Mixing/Loading Liquids for Groundboom Applicators	Wheat	2	220	590
	Corn	3	350	910
	Cotton	2	260	710
	Garlic	6	760	NA
	Onions	5	680	1,800
	Seeding Alfalfa - East	8	1000	NA
	Seeding Alfalfa - West	3	390	1,100
	Canary Grass	8	1000	NA
	Oats and Rye	8	1000	NA
	Barley	3	390	1,100
	Mint	8	1100	NA
	Sorghum	2	260	710
	Flax	6	750	NA
	Turfgrass Seed Farm	4	470	1,300
	Sod Farm	4	520	1,400
	Range Land	2	210	560
Mixing/Loading Liquids for Sprinkler Irrigation and Aerial Applications	All	1	150	400
APPLICATOR				
Groundboom Applicators	Wheat	333	450	1,000
	Corn	526	710	1,600
	Cotton	400	560	1,200
	Garlic	1,163	1,600	NA
	Onions	1,042	1,400	NA
	Seeding Alfalfa - East	1,587	2,200	NA
	Seeding Alfalfa - West	588	830	1,800

Table 20: Short-term and Intermediate-term Risks of Bromoxynil

Exposure Scenario	Crop Type	Dermal MOE[a]		
		Baseline[b]	PPE[c]	Engineering Controls[d]
Groundboom Applicators	Canary Grass	1,587	2,200	NA
	Oats and Rye	1,587	2,200	NA
	Barley	588	830	1,800
	Mint	1,667	2,300	NA
	Sorghum	400	560	1,200
	Flax	1,136	1,600	NA
	Turfgrass Seed Farm	714	1,000	NA
	Sod Farm	769	1,100	NA
	Range Land	323	430	1,000
Aerial Application - Enclosed Cockpit	All	No Data	No Data	310
FLAGGER				
Flagging Liquids	All	313	340	16,000
MIXER/LOADER/APPLICATOR[e]				
Mixing/Loading Liquids and Applying with Groundboom Equipment	Wheat	2	140	360
	Corn	3	220	560
	Cotton	2	160	430
	Garlic	6	470	1,200
	Onions	5	420	1,100
	Seeding Alfalfa - East	8	650	1,700
	Seeding Alfalfa - West	3	240	630
	Canary Grass	8	650	1,700
	Oats and Rye	8	650	1,700
	Barley	3	240	630
	Mint	8	680	1,800
	Sorghum	2	160	430
	Flax	6	460	1,200

Table 20: Short-term and Intermediate-term Risks of Bromoxynil

Exposure Scenario	Crop Type	Dermal MOE[a]		
		Baseline[b]	PPE[c]	Engineering Controls[d]
	Turfgrass Seed Farm	4	290	770
	Sod Farm	4	320	830
	Range Land	2	130	340

a Dermal MOE = NOEL (10 mg/kg/day)/Daily Dermal Dose (mg/kg/day); refer to Table 16
b PHED V1.1 based data. Baseline: handlers wearing long sleeved shirts, long pants and no gloves while using open mixing/loading and open cab tractors.
c PHED V1.1; PPE: handlers wearing long sleeved shirts, long pants and chemical resistant gloves (no gloves for applicators) while using open mixing/loading and open cab tractors; flaggers wearing coveralls over long pants, long sleeved shirts, and no gloves.
d PHED V1.1; Engineering Controls: long pants, long sleeved shirt, chemical resistant gloves for closed mixing/loading; long pants, long sleeved shirt, no gloves for enclosed cab tractor (groundboom) and inside truck (flagger); and aerial applicators wearing long pants, long sleeved shirts, and no gloves while using enclosed cockpit fixed wing airplanes (open cockpit data are not available).
e Mixer/Loader estimates + Applicator estimates; refer to Table 16

Table 21: Private Handler (grower) Cancer Risks for Bromoxynil using PHED Data

Exposure Scenario	Crop Type	Typical Rate (lb ai/A)[a]	Acres Treated/Day	Treatments per Year[a]	LADD (mg/kg/day)[b]		Cancer Risk[c]	
					Baseline[d]	PPE[d]	Baseline[d]	PPE[d]
MIXER/LOADER								
Mixing/Loading liquids for Groundboom Applications	Wheat	0.2	240	1	3.5E-04	5.1-06	**3.6E-05**	5.3E-07
	Corn	0.3	150	1	3.3E-04	4.8E-06	**3.4E-05**	4.9E-07
	Cotton	0.3	200	2	8.7E-04	1.3E-05	**9.0E-05**	1.3E-06
	Garlic	0.4	69	2	4.0E-04	5.9E-06	**4.1E-05**	6.1E-07
	Onions	0.2	77	2	2.2E-04	3.3E-06	**2.3E-05**	3.4E-07
	Seedling Alfalfa-East	0.4	50	1	1.4E-04	2.1E-06	**1.4E-05**	2.2E-07
	Seedling Alfalfa-West	0.4	133	1	3.9E-04	5.7E-06	**4.0E-05**	5.9E-07
	Canary Grass	0.5	50	1	1.8E-04	2.7E-06	**1.9E-05**	2.8E-07
	Oats and Rye	0.4	50	1	1.4E-04	2.1E-06	**1.4E-05**	2.2E-07
	Barley	0.3	133	1	2.9E-04	4.3E-06	**3.0E-05**	4.4E-07

Table 21: Private Handler (grower) Cancer Risks for Bromoxynil using PHED Data

Exposure Scenario	Crop Type	Typical Rate (lb ai/A)[a]	Acres Treated/Day	Treatments per Year[a]	LADD (mg/kg/day)[b]		Cancer Risk[c]	
					Baseline[d]	PPE[d]	Baseline[d]	PPE[d]
Mixing/Loading liquids for Groundboom Applications	Mint	0.3	48	2	2.1E-04	3.1E-06	**2.2E-05**	3.2E-07
	Sorghum	0.3	200	2	8.7E-04	1.3E-05	**9.0E-05**	1.3E-06
	Flax	0.3	70	1	1.5E-04	2.2E-06	**1.5E-05**	2.3E-07
	Turfgrass Seed Farm	0.5	111	1	4.0E-04	5.9E-06	**4.1E-05**	6.1E-07
	Sod Farm	0.5	100	2	7.2E-04	1.1E-05	**7.4E-05**	1.1E-06
	Range Land	0.5	250	1	9.0E-04	1.3E-05	**9.3E-05**	1.3E-06
Sprinkler Irrigation and Aerial Applications	All	0.5	350	1	1.2E-03	1.8E-05	**1.2E-04**	1.9E-06
APPLICATOR								
Groundboom	Wheat	0.2	240	1	1.8E-06	1.6E-06	1.9E-07	1.6E-07
	Corn	0.3	150	1	1.6E-06	1.5E-06	1.6E-07	1.5E-07
	Cotton	0.3	200	2	4.5E-06	4.2E-06	4.6E-07	4.3E-07
	Garlic	0.4	69	2	2.1E-06	1.9E-06	2.2E-07	2.0E-07
	Onions	0.2	77	2	1.1E-06	1.1E-06	1.1E-07	1.1E-07
	Seedling Alfalfa-East	0.4	50	1	7.4E-07	6.9E-07	7.6E-08	7.1E-08
	Seedling Alfalfa-West	0.4	133	1	1.9E-06	1.8E-06	2.0E-07	1.9E-07
	Canary Grass	0.5	50	1	9.3E-07	8.7E-07	9.6E-08	9.0E-08
	Oats and Rye	0.4	50	1	7.4E-07	6.9E-07	7.6E-08	7.1E-08
	Barley	0.3	133	1	1.5E-06	1.4E-06	1.5E-07	1.4E-07
	Mint	0.3	48	2	1.1E-06	1.0E-06	1.1E-07	1.0E-07
	Sorghum	0.3	200	2	4.5E-06	4.2E-06	4.6E-07	4.3E-07
	Flax	0.3	70	1	7.9E-07	7.3E-07	8.1E-08	7.5E-08
	Turfgrass Seed Farm	0.5	111	1	2.1E-06	1.9E-06	2.2E-07	2.0E-07
	Sod Farm	0.5	100	2	3.8E-06	3.5E-06	3.9E-07	3.65E-07
	Range Land	0.5	250	1	4.7E-06	4.4E-06	4.8E-07	4.5E-07

Table 21: Private Handler (grower) Cancer Risks for Bromoxynil using PHED Data

Exposure Scenario	Crop Type	Typical Rate (lb ai/A)[a]	Acres Treated/Day	Treatments per Year[a]	LADD (mg/kg/day)[b]		Cancer Risk[c]	
					Baseline[d]	PPE[d]	Baseline[d]	PPE[d]
Aerial Application - Enclosed Cockpit	All	0.5	350	1	6.5E-06	6.0E-06	6.7E-07	6.2E-07
FLAGGERS								
Flagging liquids	All	0.5	350	1	4.3E-06	3.0E-06	4.4E-07	3.1E-07
MIXER/LOADER/APPLICATOR[e]								
Mixing/Loading Liquids and Applying with Groundboom Equipment	Wheat	0.2	240	1	3.5E-04	6.8E-06	**3.6E-05**	7.0E-07
	Corn	0.3	150	1	3.3E-04	6.4E-06	**3.4E-05**	6.6E-07
	Cotton	0.3	200	2	8.7E-04	1.7E-05	**9.0E-05**	1.8E-06
	Garlic	0.4	69	2	4.0E-04	7.9E-06	**4.1E-05**	8.1E-07
	Onions	0.2	77	2	2.2E-04	4.4E-06	**2.3E-05**	4.5E-07
	Seedling Alfalfa-East	0.4	50	1	1.4E-04	2.9E-06	**1.4E-05**	3.0E-07
	Seedling Alfalfa-West	0.4	133	1	3.9E-04	7.5E-06	**4.0E-05**	7.7E-07
	Canary Grass	0.5	50	1	1.8E-04	3.6E-06	**1.9E-05**	3.7E-07
	Oats and Rye	0.4	50	1	1.4E-04	2.9E-06	**1.4E-05**	3.0E-07
	Barley	0.3	133	1	2.9E-04	5.7E-06	**3.0E-05**	5.9E-07
	Mint	0.3	48	2	2.0E-04	4.1E-06	**2.1E-05**	4.2E-07
	Sorghum	0.3	200	2	8.1E-04	1.7E-05	**9.0E-05**	1.8E-06
	Flax	0.3	70	1	1.5E-04	3.0E-06	**1.5E-05**	3.1E-07
	Turfgrass Seed Farm	0.5	111	1	4.0E-04	7.9E-06	**4.1E-05**	8.1E-07
	Sod Farm	0.5	100	2	7.2E-04	1.4E-05	**7.4E-05**	1.4E-06
	Range Land	0.5	250	1	9.0E-04	1.7E-05	**9.3E-05**	1.8E-06

a Typical Annual Usage for Bromoxynil; May 1996, Halvorson, A. BEAD/EPA.

b LADD (mg/kg/day) = [(Daily Dose (mg/kg/day) x (Treatments per year)/365 days per year)] x [40work-yrs/75 yrs-lifetime] x [0.10 dermal absorption factor]

c Cancer Risk = LADD (mg/kg/day) x Q_1^*(mg/kg/day)$^{-1}$; where $Q_1^* = 1.03 \times 10^{-1}$ (mg/kg/day)$^{-1}$

d PHED V 1.1 based data. Baseline: handlers wearing long sleeved shirts, long pants and no gloves while using open mixing/loading and open cab tractors. PPE: handlers wearing long sleeved shirts, long pants and chemical resistant gloves while using open mixing/loading and open cab tractors; flaggers wearing coveralls over long pants, long sleeved shirts, and no gloves; aerial applicators wearing long pants, long sleeved shirts, and no gloves while using enclosed cockpit fixed wing airplanes (open cockpit data are not available).

e Mixer/Loader estimates + Applicator estimates

Table 22: Commercial Handler Cancer Risks for Bromoxynil Using PHED Data

Exposure Scenario	Crop Type	Typical Rate (lb ai/A)[a]	Treatments per Year[a]	LADD (mg/kg/day)[b]		Cancer Risk[c]	
				Baseline[d]	PPE[d]	Baseline[d]	PPE[d]
MIXER/LOADER							
Groundboom Applications	Wheat	0.2	21	7.2E-03	1.2E-04	**7.4E-04**	**1.3E-05**
	Corn	0.3	20	6.5E-03	7.4E-05	**6.7E-04**	7.6E-06
	Canary Grass	0.5	21	3.8E-03	2.6E-05	**3.9E-04**	2.7E-06
	Oats and Rye	0.4	21	3.0E-03	2.6E-05	**3.1E-04**	2.7E-06
	Barley	0.3	21	5.9E-03	6.9E-05	**6.1E-04**	7.1E-06
	Sorghum	0.3	14	6.0E-03	6.9E-05	**6.2E-04**	7.1E-06
	Flax	0.3	7	1.0E-03	1.2E-05	**1.0E-04**	1.3E-06
Sprinkler Irrigation and Aerial Applications	All	0.5	21	2.7E-02	1.8E-04	**2.8E-03**	**1.9E-05**
APPLICATOR							
Groundboom	Wheat	0.2	21	3.8E-05	3.5E-05	3.9E-06	3.6E-06
	Corn	0.3	20	3.3E-06	3.3E-05	3.4E-07	3.4E-06
	Canary Grass	0.5	21	1.9E-05	1.9E-05	2.0E-06	2.0E-06
	Oats and Rye	0.4	21	1.5E-05	1.5E-05	1.5E-06	1.5E-06
	Barley	0.3	21	3.1E-05	2.9E-05	3.2E-06	3.0E-06
	Sorghum	0.3	14	3.1E-05	3.0E-05	3.2E-06	3.1E-06
	Flax	0.3	7	5.5E-06	5.2E-06	5.7E-07	5.4E-07
Aerial Application - Enclosed Cockpit	All	0.5	21	No Data	4.7E-05	No Data	4.8E-06
FLAGGERS							
Flagging liquids	All	0.5	21	9.1E-05	6.2E-05	9.4E-06	**6.4E-06**

a Typical Annual Usage for Bromoxynil; May 1996, Halvorson, A. BEAD/EPA.

b LADD (mg/kg/day) = [(Daily Dose (mg/kg/day) x (Treatments per year)/365 days per year)] x [40work-yrs/75 yrs-lifetime] x [0.10 dermal absorption factor]

c Cancer Risk = LADD (mg/kg/day) x Q_1^*(mg/kg/day)$^{-1}$; where $Q_1^* = 1.03 \times 10^{-1}$ (mg/kg/day)$^{-1}$

d PHED V 1.1 based data. Baseline: handlers wearing long sleeved shirts, long pants and no gloves while using open mixing/loading and open cab tractors. PPE: handlers wearing long sleeved shirts, long pants and chemical resistant gloves while using open mixing/loading and open cab tractors; flaggers wearing coveralls over long pants, long sleeved shirts, and no gloves; aerial applicators wearing long pants, long sleeved shirts, and no gloves while using enclosed cockpit fixed wing airplanes (open cockpit data are not available).

Based on use of the PHED V1.1 data the calculations of risk indicate that the MOEs for short-term and intermediate-term exposures are greater than 100 for all scenarios either at baseline or, in the case of mixers/loaders, when chemical-resistant gloves are worn. The cancer risk for the Private Handler (grower) is 2×10^{-6} or lower for all the scenarios for all scenarios either at baseline or, in the case of mixers/loaders, when chemical-resistant gloves are worn. The cancer risk for Commercial Handlers is 1.9×10^{-5} and lower for all scenarios for all scenarios either at baseline or, in the case of mixers/loaders, when chemical-resistant gloves are worn. These risk estimates do not account for the potential exposure reduction from the use of "wide-mouth" containers (designed to reduce spillage) for mixer/loaders. At the present time the PHED database does not allow the Agency to quantify this risk mitigation measure. Therefore, the use of the "wide-mouth" containers may reduce the risk further.

Estimates of Dermal Risks from Short-Term Exposures Using PHED Data

The calculations of risk based on PHED V1.1, which are considered medium to high grade data, indicate that the MOEs are greater than 100 for the following scenarios:

- mixers/loaders handling liquids supporting groundboom, aerial and sprinkler irrigation applications using open loading systems and wearing chemical-resistant gloves in addition to long-sleeve shirts, long pants, shoes, and socks;
- applicators using open-cab groundboom equipment while wearing long-sleeve shirts and long pants, shoes, and socks and no gloves;
- all flaggers supporting aerial applications while wearing long-sleeve shirts, long pants and no gloves;
- mixer/loader/applicators handling liquids and performing groundboom applications using open loading systems and open cab tractors when mixers/loaders are wearing chemical-resistant gloves in addition to long-sleeve shirts, long pants, shoes, and socks and applicators are wearing long-sleeve shirts, long pants, shoes, and socks;
- all aerial applicators using enclosed-cockpit aircraft while wearing long-sleeve shirts, long pants, and no gloves.

Estimates of Cancer Risks Using PHED Data

The calculations of cancer risk based on PHED V1.1, which are considered medium to high grade data, indicate that the cancer risks are less than or approximately equal to 1×10^{-6} for the following private applicator (grower) scenarios:

- all mixers/loaders supporting all applications using open loading systems and wearing chemical-resistant gloves in addition to long-sleeve shirts and long pants;
- all applicators using open-cab groundboom equipment and wearing long-sleeve shirts and long pants;
- all aerial applicators using enclosed-cockpit aircraft and wearing long-sleeve shirts and long pants (note: no open-cockpit data are available);
- all flaggers supporting aerial applications and wearing long-sleeve shirts and long pants;

- all mixer/loader/applicators mixing liquids and applying with groundboom equipment using open loading systems and open-cab equipment with mixers/loaders wearing chemical-resistant gloves in addition to long-sleeve shirts, long pants, shoes, and socks and applicators wearing long-sleeve shirts, long pants, shoes, and socks.

The calculations of cancer risk based on PHED V1.1 data indicate that the cancer risks are less than or approximately equal to 1×10^{-5} for the following commercial handler scenarios:

- all mixers/loaders supporting all groundboom applications using open loading systems and wearing chemical-resistant gloves in addition to long-sleeve shirts and long pants, shoes, and socks;
- all applicators using open-cab groundboom equipment and wearing long-sleeve shirts and long pants, shoes, and socks;
- all aerial applicators using enclosed-cockpit aircraft and wearing long-sleeve shirts and long pants, shoes, and socks (note: no open-cockpit data are available);
- all flaggers supporting aerial applications and wearing long-sleeve shirts and long pants, shoes, and socks;
- mixer/loader/applicators supporting groundboom applications to garlic, onions, seeding alfalfa in the East, canary grass, oats and rye, mint, and flax while using closed loading systems and enclosed cab equipment and wearing chemical-resistant gloves (mixing/loading only) in addition to long-sleeve shirts and long pants, shoes, and socks.

For commercial handlers mixing/loading to support aerial applications and mixing/applying for sprinkler-irrigation applications, the estimated cancer risk (calculated with PPE) based on PHED data is 1.9×10^{-5}, which is below EPA's level of concern for occupational scenarios.

b. Postapplication Exposures and Risk

EPA has determined that there is potential exposure to persons entering treated sites after application is complete. Post application exposures may occur to *i*) workers following applications to agricultural crops during routine crop production practices (e.g., cultivation, scouting, hoeing), *ii*) workers entering treated commercially grown sod, *iii*) golf course maintenance workers following applications to turfgrass, *iv*) landscape and ground maintenance workers following applications to commercial/industrial areas and other no-crop areas.

There are no postapplication exposure data available at this time to determine potential risks from bromoxynil uses. In lieu of chemical-specific data, a surrogate range-finder postapplication exposure assessment was performed for occupational settings.

The range finder assessment in Table 23 is based on the application rate of 0.5 lb ai/A for all crops. The transfer coefficients (Tc) range from low exposure potentials such as hoeing in various field crops (500 cm^2/hr) and scouting early season cotton (1,000 cm^2/hr) to high exposure potentials such as harvesting sod (10,000 cm^2/hr). Assuming an acceptable MOE of 100, the restricted entry interval (REI) ranges from 0 days to 26 days.

Table 23: Bromoxynil Short-Term and Intermediate-Term Postapplication Occupational Surrogate Assessment (Range Finder)

DAT[a]	DFR (μg/cm^2)[b]	Dermal Dose (mg/kg/day)[c]		MOE[d]	
		Low	High	Low	High
All Crops Except Cotton					
0	1.12	0.075	1.49	130	7
26	0.72	0.005	0.097	2000	100
Cotton (0.5 lb ai/A)					
0	2.2	0.30	1.2	33	NA
4	0.78	0.10	0.42	100	NA

a DAT = Days after treatment.

b DFR (μg/cm^2) = Appl. rate (lb ai/A) x 11.209 (μg per cm^2/lb ai per acre conversion) x 0.2 (fraction of ai retained on foliage). A dissipation rate of 10 percent per day is assumed.

c Dermal Dose (mg/kg/day) = DFR (μg/cm^2) x T_c (cm^2/hr) x 1 mg/1,000 μg conversion) x 8 (hrs/day) / 60 kg BW. Where LOW potential exposure = 500 to 1,000 cm^2/hr and High potential exposure = 10,000 cm^2/hr.

d MOE = NOEL (mg/kg/day) / Dermal Dose (mg/kg/day). Where NOEL = 10 mg/kg/day.

Bromoxynil is a contact herbicide and should be applied while weeds are actively growing. The application timing for crops like corn and small grains, which comprise approximately 90% of bromoxynil usage, is early in the season (from preemergence to prior to tassel emergence/boot stage). Because of the use patterns and mode of action of bromoxynil, most workers entering treated fields would likely be performing scouting tasks or low contact labor tasks such as mechanical incorporation and cultivation. One likely exception is workers entering transgenic cotton fields. The window of application for transgenic cotton is wider, which increases the potential for worker contact with treated surfaces and cotton is scouted frequently. Another likely exception is post-application exposures to workers entering commercially grown sod areas. The sod may be harvested soon after an application, which could result in relatively high post-application exposures.

Based on the surrogate assessment, the Agency has concerns regarding low exposure activities for cotton and high exposure activities for crops other than cotton (e.g., harvesting sod for applications less than 26 days from harvest). The interim REI established by the WPS is 24 hours. Since the toxicological endpoint for short-term and intermediate-term exposure is based on a NOEL for developmental effects, EPA is concerned that the default REI of 24 hours is not protective enough, especially for cotton workers and sod harvesters where there is significant potential for postapplication exposures. This document reiterates the **REIs of 4 days for cotton and 26 days for sod** established in the Federal Register Notice published May 13, 1998 in conjunction with the cotton use registration action.

It is the short-term exposure driving the risk estimate for reentry concerns so EPA believes any measures to reduce short term risks will be protective for cancer risks.

c. Epidemiological Information

Only a limited number of incidents involving the use of bromoxynil alone have been reported. Eye or skin illnesses were the most frequently reported in the 11 cases received by the California

Pesticide Illness Surveillance Program from 1982-1993, inclusively. The number of systemic incidents per 1,000 applications for 1990 was 0 based on California use data (beginning in 1990 all agricultural uses had to be reported, prior to that only data on restricted use applications were required). The ratio of systemic poisonings to applications for all years is generally low when compared to organophosphate and carbamate insecticides. No recommendations for risk mitigation are warranted based on the limited data available on poisoning incidents.

C. Environmental Assessment

The environmental assessment consists of four sections: Ecological Toxicity, Environmental Fate and Transport, Ecological Exposure and Risk Assessment, and Environmental Risk Characterization. The first and third sections report the ecological toxicity data from laboratory studies, estimate ecological exposure and assess the effects to nontarget terrestrial and aquatic organisms. The second section depicts the environmental fate and transport data from field and laboratory studies, analyzes the impact to water resources, and details the environmental fate assessment. The section on environmental risk characterization integrates the exposure and effects assessments to determine the extent and potential for risk to the environment.

1. Ecological Toxicity Data

The Agency has adequate data to assess acute and chronic hazard of bromoxynil octanoate to nontarget species. In the risk assessment, toxicity data for bromoxynil octanoate, with the exception of aquatic vascular plants, was used to estimate risk. This is consistent with the fate information. In most cases, bromoxynil octanoate was more toxic to test species than bromoxynil heptanoate.

The guideline requirements for Tier 2 aquatic plant testing for bromoxynil octanoate (GLN 123-2) are only partially fulfilled. Data must be submitted to fulfill the guideline requirement for *Lemna gibba* (aquatic macrophyte). Additional data for chronic estuarine toxicity (72-4) are needed as confirmatory data to complete the chronic assessment.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

An oral (LD_{50}) study (preferably mallard duck or bobwhite quail) and two subacute dietary (LC_{50}) studies (one species of waterfowl, preferably the mallard duck, and one species of upland game bird, preferably bobwhite quail) are required to establish the acute and subacute toxicity of a pesticide to birds. Results of these tests are tabulated below.

Table 24: Avian Acute Oral Toxicity Findings

Species	% A.I. derivative	LD_{50} (mg ai/kg)	MRID or Acc. No. Author, Yr	Toxicity Category	Fulfills Guideline Requirement
Bobwhite Quail	87.3 octanoate	148	Acc. # 248229 Fletcher, 1981	moderately toxic	Yes
Bobwhite Quail	89.3 phenol	193	Acc. # 258887 Fletcher, 1985	moderately toxic	Yes
Bobwhite Quail	94.8 heptanoate	359	43030001 Campbell, 1993	moderately toxic	Yes
Mallard Duck	87.3 octanoate	2050	Acc.# 248229 Fletcher, 1981	practically non-toxic	Yes

Table 25: Avian Subacute Dietary Toxicity Findings

Species	% A.I. derivative	LC_{50} (ppm ai)	MRID or Acc. No. Author, Year	Toxicity Category	Fulfills Guideline Requirment
Bobwhite Quail	94.8 heptanoate	4530	43030002 Campbell, 1993	slightly toxic	Yes
Bobwhite Quail	87.3 octanoate	1150	Acc.# 248229 Fletcher, 1982	slightly toxic	Yes
Bobwhite Quail	89.3 phenol	1790	Acc. # 258886 Fletcher, 1985	slightly toxic	Yes
Mallard Duck	87.3 octanoate	1880	Acc.# 248229 Fletcher, 1981	slightly toxic	Yes
Mallard Duck	89.3 phenol	1230	Acc. # 258888 Fletcher, 1985	slightly toxic	Yes
Ring-necked Pheasant	technical octanoate	4400	Acc.# 247924 Harper, 1965	slightly toxic	Yes
Ring-necked Pheasant	36.6 octanoate	1830	Acc.# 247924 Harper, 1965	slightly toxic	Yes

These results indicate that bromoxynil (phenol), heptanoate, and octanoate are moderately toxic to practically non-toxic to avian species on an acute oral basis and slightly toxic to avian species on a subacute dietary basis. The guideline requirements (71-1(a) and 71-2(a) & (b)) are fulfilled (Accession No. 248229, 258887, 258886, 247924, and 258888).

(2) Birds, Chronic

Avian reproduction studies are required for bromoxynil octanoate because it may be applied two times per use season on several crops, and up to three times per season on cotton. Results of this test are tabulated below.

Table 26: Avian Reproduction Findings

Species	% A.I.	NOEL ppm	LOEL ppm	Endpoints affected	MRID No. Author, Year	Fulfills Guideline Requirement
Northern Bobwhite	97.2 octanoate	371	NA	NA	42004101,42475801 Beavers, 1991	Yes[1]
Mallard Duck	97.2 octanoate	102	340	number of eggs laid and set, number of viable embryos, number of live 3-week embryos, and lesions of old yolk peritonitis or regressing ovary	42004102 Beavers, 1991	Yes

[1] This study fulfills the guideline requirement even though it is classified as supplemental.

The results indicate that bromoxynil octanoate can impair the reproduction of birds at dietary concentrations greater than 102 ppm. The guideline requirements (71-4(a) & (b)) are fulfilled for bromoxynil octanoate (MRID 42004101, 42475801, and 42004102).

b. Mammals

Data from available mammalian studies which are used for human health risk assessment will be used to estimate toxicity to wild mammalian species. A rat acute oral LD_{50} study with bromoxynil octanoate resulted in an LD_{50} of 238 mg/kg for female rats and 400 mg/kg for male rats. These results indicate that bromoxynil octanoate is moderately toxic to small mammals on an acute oral basis. (MRID 124112)

A two-generation rat reproduction study with the technical grade of bromoxynil octanoate (97.8 - 98.1% a.i.) reported a reproductive NOEL of 250 ppm and a systemic LOEL greater than 250 ppm based on reduced body weight gain in females. (83-4, MRID 41149301) A two-generation rat reproductive study with the technical grade of bromoxynil phenol reported a reproductive NOEL of 50 ppm based on decreased body weight of offspring (MRID #41149301).

c. Insects

A honeybee acute contact LD_{50} study was submitted for bromoxynil octanoate due to its extensive use on cotton and other agricultural sites. A honeybee acute contact study showed that bromoxynil octanoate (formulation not identified) is practically nontoxic to honeybees with an LD_{50} of 14.5 μg ai/bee. There is sufficient information to characterize bromoxynil octanoate as practically non-toxic to bees. The guideline requirement (141-1) is fulfilled. (ID No. 00018842)

d. Toxicity to Aquatic Animals

(1) Freshwater Fish

Two freshwater fish toxicity studies using the technical grade of the active ingredient are required to establish the toxicity of a pesticide to freshwater fish. One study should use a coldwater species (preferably the rainbow trout), and the other should use a warmwater species (preferably the bluegill sunfish). Results of these tests are tabulated below.

Table 27: Freshwater Fish Acute Toxicity Findings

Species	% A.I. derivatives	LC_{50} (ppb a.i.)	MRID No. Author, Year	Toxicity Category	Fulfills Guideline Requirement
Rainbow Trout	36.6 octanoate	50	Acc. # 247924 Harper, 1965	very highly toxic	Yes
Rainbow Trout	87.3 octanoate	100	Acc. # 264229 Sousa, 1981	highly toxic	Yes
Rainbow Trout	21.5 phenol	3870	Acc. # 072254 Hoberg, 1983	moderately toxic	Yes
Rainbow Trout	95 phenol	2100	Acc. # 260441 Nicholson, 1985	moderately toxic	Yes
Bluegill Sunfish	94.8 heptanoate	29	43059601 Bettencourt, 1993	very highly toxic	Yes
Bluegill Sunfish	87.3 octanoate	53	Acc. # 248229 Sousa, 1981	very highly toxic	Yes
Bluegill Sunfish	95 phenol	4000	Acc. # 260441 Nicholson, 1985	moderately toxic	Yes
Bluegill Sunfish	21.5 phenol	4945	Acc. # 072336 Sousa, 1983	moderately toxic	Yes
Catfish (*Ictalurus nebulosus*)	36.6 octanoate	23	Acc. # 247924 Harper and Ball, 1965	very highly toxic	No, supplemental
Goldfish	36.6 octanoate	170	Acc. # 247924 Harper and Ball, 1965	highly toxic	No, supplemental

The results of the 96-hour acute toxicity studies indicate that bromoxynil octanoate is very highly toxic, bromoxynil heptanoate is very highly toxic, and bromoxynil phenol is moderately toxic to

freshwater fish. The guideline requirements (72-1(a) & (c)) are fulfilled. (Accession 247924, 072336, 260441, 248229, 072254, 264229, 247924)

Data from fish early life-stage tests are required because bromoxynil octanoate is very highly toxic to freshwater fish on an acute basis (acute LC_{50}s range from 23 - 100 ppb). Results of this test are tabulated below.

Table 28: Fish Early Life-Stage Toxicity Findings

Species	% A.I.	NOEL (ppb)	LOEL (ppb)	MATC (ppb)	MRID No. Author/Year	Endpoint Affected	Fulfills Guideline Requirement
Fathead minnow	97.2 octanoate	18	39	26	41928301 Sousa, 1991	decreased larval growth, survival and embryo hatching success	Yes, supplemental
Fathead minnow	63 octanoate	9	18	12	40111003 Suprenant, 1987	decreased larval survival	No

One of the chronic fish studies is supplemental, but taken in conjunction with the previous early life-stage fish study conducted in 1987 (MRID 40111003) they satisfy the guideline requirement (72-4(a)). The results indicate that reproductive effects of bromoxynil octanoate to freshwater fish may occur at levels greater than 9 ppb. The guideline requirement (72-4(a)) is fulfilled. (MRID 41928301, 40111003)

(2) Freshwater Invertebrates

A freshwater aquatic invertebrate toxicity test using the technical grade of the active ingredient is required to assess the toxicity of a pesticide to freshwater invertebrates. The preferred test organism is *Daphnia magna*, but early instar amphipods, stoneflies, mayflies, or midges may also be used. Results of this test are tabulated below.

Table 29: Freshwater Invertebrate Toxicity Findings

Species	% A.I.	EC_{50} (ppb ai)	MRID NO. Author, Year	Toxicity Category	Fulfills Guideline Requirement
Daphnia magna (daphnid)	87.3 octanoate	96	Acc. # 248229 Suprenant, 1981	very highly toxic	Yes
Daphnia pulex (daphnid)	36.6 octanoate	11	Acc. # 247924 Harper, 1964	very highly toxic	Yes
Daphnia magna (daphnid)	94.8 heptanoate	31	43059602 Putt, 1993	very highly toxic	Yes
Daphnia magna (daphnid)	95 phenol	19,220	Acc. # 260441 Nicholson, 1985	slightly toxic	Yes
Daphnia magna (daphnid)	21.5 phenol	15,910	00138087 Hoberg, 1983	slightly toxic	Yes

The results indicate that bromoxynil octanoate and heptanoate are very highly toxic and bromoxynil phenol is slightly toxic to aquatic invertebrates. The guideline requirement (72-2(a)) is fulfilled. (Accession No. 247924, 260441, 248229, MRID 00138087)

Data from an aquatic invertebrate life-cycle test using Daphnia magna are required because bromoxynil octanoate is very highly toxic to Daphnia magna (EC_{50} of 11-96 ppb), is registered for uses that involve multiple applications, and has a half-life of greater than 4 days. Results of this test are tabulated below.

Table 30: Aquatic Invertebrate Life-Cycle Toxicity Findings

Species	% A.I.	NOEL ppb ai	LOEL ppb ai	MATC ppb ai	MRID No. Author/Year	Endpoint Affected	Fulfills Guideline Requirement
Daphnia magna (daphnid)	97.2 octanoate	2.5	5.9	3.8	41928302 Putt, 1991	reproduction and growth	Yes
Daphnia magna (daphnid)	60 octanoate	2.6	5.3	3.7	40111001 Suprenant, 1986	survival	Yes

Both aquatic invertebrate studies are supplemental individually, but taken together they satisfy the guideline requirement for a life-cycle aquatic invertebrate study. The results indicate that aquatic invertebrate reproductive impairment may occur at bromoxynil octanoate levels greater than 2.5 ppb. The guideline requirement (72-4(b)) is fulfilled. (MRID 41928302, 40111001)

(3) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms (fish, shrimp and oyster embryo-larvae or shell deposition) using the technical grade of the active ingredient is required for bromoxynil octanoate because of aerial application and because it has use patterns associated with estuarine and marine environments. Results of these tests are tabulated below.

Table 31: Estuarine/Marine Acute Toxicity Findings

Species	% A.I.	LC_{50} or EC_{50} (ppb ai)	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Eastern oyster (shell deposition)	92.4 octanoate	155	42244501 Dionne, 1992	highly toxic	Yes
Mysid	94.9 octanoate	65	43487601 Machado, 1994	very highly toxic	Yes
Sheepshead minnow	97.2 octanoate	170	42250601 Machado, 1992	highly toxic	Yes

The results indicate that bromoxynil octanoate is highly toxic to estuarine/marine fish and oysters and very highly toxic to estuarine/marine shrimp on an acute basis. The guideline requirements (72-3 (a) & (c)) are fulfilled. (MRID 42244501, 42250601, 43487601).

Chronic testing with bromoxynil octanoate for estuarine/marine organisms (172-4 (a) & (b)) has not been submitted and is requested at this time.

e. Toxicity to Plants

(1) Terrestrial

Terrestrial plant testing (seedling emergence and vegetative vigor) is required for all herbicides.

For the seedling emergence and vegetative vigor testing, the following plant species and groups should be tested: (1) six species of at least four dicotyledonous families, one species of which is soybean (Glycine max), and the second of which is a root crop, and (2) four species of at least two monocotyledonous families, one of which is corn (Zea mays). Results of these studies are tabulated below.

Table 32: Tier 2 toxicity data on the TEP material for the most sensitive species:

Study Type	% AI	Species	EC_{25} (lb ai/A)	Most Sensitive Endpoint	MRID # Author, Year	Fulfills Guideline Requirements
Germination	97.6 octanoate	dicot -- tomato	>0.45	germination, radicle length	43273801 Hoberg, 1994	Yes
		all monocots tested	>0.45	germination, radicle length		
Seedling Emergence	94.8 heptanoate	dicot -- lettuce	0.014	shoot length	43059603 Hoberg, 1993	Yes
		all monocots tested	>0.45	shoot length		
Vegetative Vigor	94.8 heptanoate	cabbage	0.011	shoot weight	43059603 Hoberg, 1993	Yes
		ryegrass	0.19	root weight		
Seedling Emergence	33.58 octanoate (Buctril)	dicot --tomato	0.12	shoot length	43633701 Hoberg, 1995	Yes
		all monocots tested	> 0.60	emergence, shoot length		
Vegetative Vigor	33.58 octanoate (Buctril)	dicot--tomato, cabbage	0.017	plant dry weight	43633701 Hoberg, 1995	Yes
		monocot--onion	0.37	plant dry weight		

The results indicate that non-target terrestrial plants may be affected from runoff if the soil residues exceed an equivalent of 0.12 lb ai/A and from drift if the drift residues exceed 0.017 lb ai/A. The guideline requirements (123-2) are fulfilled for seedling emergence and for vegetative vigor. (MRID 43633701)

(2) Aquatic Plant

Currently, aquatic plant testing is required for all herbicides. The following species should be tested: *Selenastrum capricornutum, Lemna gibba, Skeletonema costatum, Anabaena flos-aquae,* and a freshwater diatom. The results are tablulated in the table below.

Table 33: Tier II toxicity data on the technical material

Species	% A.I.	EC_{50} (ppb ai)	MRID NO. Author/year	Fulfills Guideline Requirement
Lemna gibba	94.8 heptanoate	219	43059604 Hoberg, 1993	Yes
Selenastrum capricornutum (green algae)	94.8 heptanoate	80	43059605 Hoberg, 1993	Yes
Navicula pelliculosa (Freshwater diatom)	97.2 octanoate	51	41606001 Giddings, 1990	Yes
Selenastrum capricornutum (green algae)	97.2 octanoate	210	41606004 Giddings, 1990	Yes
Skeletonema costatum (marine diatom)	97.2 octanoate	140	41606002 Giddings, 1990	Yes
Anabaena flos-aquae (blue-green algae)	97.2 octanoate	> 630	41606005 Giddings, 1990	Yes

The results indicate that algae and diatoms are sensitive to bromoxynil octanoate and heptanoate. The guideline requirements for Tier 2 aquatic plant testing for bromoxynil octanoate (GLN 123-2) are only partially fulfilled. Acceptable data have not been submitted for *Lemna gibba*. These data must be submitted to fulfill the guideline requirement. (MRID 4160601, 41606002, 41606004, and 41606005)

2. Environmental Fate

a. Environmental Fate Assessment

Bromoxynil octanoate was found to be chemically and physically similar to bromoxynil heptanoate (one carbon difference in the ester side chain) and both esters readily hydrolyze to 3,5-dibromo-4-hydroxybenzonitrile [referred to as bromoxynil (phenol)] which further degrades to CO_2. Bromoxynil octanoate is mobile and non-persistent. It dissipates in the environment by abiotic hydrolysis, photolytic degradation, and microbially-mediated metabolism in both the aerobic and anaerobic environments. The heptanoate ester was registered based on bridging data for bromoxynil octanoate.

Laboratory studies indicate that bromoxynil octanoate is non-persistent. The hydrolysis of bromoxynil octanoate is base-catalyzed with half-lives of 34.1, 11.5 and 1.7 days at pH 5, 7 and 9, respectively. The major hydrolytic degradate is bromoxynil (phenol). Bromoxynil octanoate also degrades via aqueous photolysis with a half-life of 4.6 days at pH 5. Soil photolysis is comparable to aqueous photolysis with a reported half-life of 2.6 days. Bromoxynil octanoate is non-persistent and degrades by microbially-mediated metabolism under both aerobic and anaerobic conditions. The calculated half-life from the aerobic soil metabolism study is 2 days while the half-life from the anaerobic aquatic metabolism study is 3.7 days. The aerobic aquatic metabolism study also shows rapid degradation with a half-life of <12 hours.

The unaged soil column leaching study indicates that bromoxynil octanoate is mobile in columns of sand, sandy loam, and loam soils. Residues were distributed throughout the length of each soil column and ranged from 2.7-18.2% of the applied in the leachates for the sandy loam and loam soils, and 52.4-58.9% of the applied in the leachates for the sand soils. The aged soil column leaching study indicates that bromoxynil octanoate residues are not mobile in four soils and aquatic sediment. Supplemental information shows that bromoxynil octanoate has a Kd of 7.0 ml/g (Koc of 1,003) in soils with 1.2% organic matter; however, without a range of Kd (and due to the fact that this is a supplemental study) it is difficult to assess the mobility.

The observed half-life of bromoxynil octanoate in a terrestrial field dissipation study conducted in California was approximately 14 days while a half-life of 1 day was reported for a North Carolina field site.

Bromoxynil octanoate bioaccumulates in bluegill sunfish with bioconcentration factors of 63X for edible tissue, 400X for inedible tissue, and 230X for whole fish; however, depuration occurred in 14 days.

Bromoxynil octanoate does not exhibit the mobility or persistence characteristics of pesticides that are normally found in ground water. Based on limited monitoring information, residues of bromoxynil octanoate have not been detected in ground water. Based on information from environmental fate studies, bromoxynil octanoate should not persist in surface waters. Limited monitoring information is available.

b. Environmental Fate and Transport

(1) Degradation

Abiotic Hydrolysis

Hydrolysis of bromoxynil octanoate is base-catalyzed with half-lives of 34.1 days at pH 5, 11.5 days at pH 7, and 1.7 days for pH 9. The hydrolysis products were 3,5-dibromo-4-hydroxybenzonitrile (referred to as bromoxynil (phenol)), and 3,5-dibromo-dihydroxy-cyclohexadienylnitrile. Bromoxynil (phenol), which is stable to hydrolysis, increased throughout the study, reaching maximum concentrations at 30 days of 35%, 77%, and 76% at pH 5, 7, and 9, respectively. The degradate 3,5-Dibromo-dihydroxy-cyclohexadienylnitrile concentrations reached maximum concentrations of 10.4%, 10.7%, and 7.9% at pH 5, 7 and 9, respectively, but declined from those values by the end of the study, indicating that it was not stable to hydrolysis. This data requirement is fulfilled (GLN 161-1; MRID 41892901).

In another study bromoxynil octanoate hydrolyzed with calculated half-lives of 43 days at pH 5, 28 days at pH 7, and 1.5 days for pH 9. Hydrolysis of bromoxynil butyrate (an ester of bromoxynil which is currently not being registered) is base-catalyzed with calculated half-lives of 44 days at pH 5, 52 days at pH 7, and 1.1 days for pH 9. Bromoxynil (phenol) was the hydrolysis product for both the octanoate and the butyrate. It was stable to hydrolysis at pH 5, 7, and 9. The study was considered acceptable. This data requirement is fulfilled (GLN 161-1; MRID 00130424).

Aqueous Photolysis

Bromoxynil octanoate degraded with a calculated photolytic half-life of 4.6 days at pH 5. Each photoperiod consisted of 12 hours of light (artificial - xenon arc lamp) and 12 hours of darkness. Bromoxynil octanoate was stable in the dark controls with a 110.7-day half-life. In the irradiated samples there were 3 major degradates: 4-cyano-2-bromophenyl octanoate (maximum mean concentration of 13.9% at day 3), bromoxynil (phenol) (maximum mean concentration of 53.4% at day 30), and phenyl carbamate (maximum mean concentration of 26.6% at day 2). This data requirement is fulfilled (GLN 161-2; MRID 42234301 and 41920401).

Soil Photolysis

Bromoxynil octanoate degraded with a calculated photolytic half-life of 2.6 days in the irradiated samples (artificial - xenon arc lamp) and 3.6 days in the dark control. The 3.6 day half-life in the dark controls suggests other degradation processes such as hydrolysis or microbial metabolism, were occurring. This data guideline requirement is fulfilled (GLN 161-3; MRID 41920402).

Aerobic Soil Metabolism

[Cyano labeled ^{14}C]-bromoxynil octanoate degraded in a sandy loam soil with a calculated half-life of 2 days. The major degradate was CO_2 which accounted for 64.28% of the applied radioactivity at 90 days. (GLN 162-1; MRID 42234302 and MRID 41897701). Bromoxynil (phenol) exhibited half-lives of 51 hr in sandy loam and 31 hr in loam soils (GLN 162-1; MRID 00142958). This data requirement is fulfilled (GLN 162-1; MRID 42234302, 41897701 and 00142958).

Anaerobic Aquatic Metabolism

Bromoxynil octanoate degraded in a sandy loam sediment with a calculated half-life of 3.7 days based on the results obtained over the first 14 days of the experiment. The degradate 4-hydroxybenzonitrile reached a maximum concentration of 45.52% by Day 14 before decreasing to 0.14% at 26 weeks. Bromoxynil (phenol) was also formed, reaching a maximum concentration of 48.5% by day 7, then decreasing to 3.5% at 8 weeks. This data requirement is fulfilled (GLN 162-3; MRID 42234303 and 41892902).

Aerobic Aquatic Metabolism

Bromoxynil octanoate degraded with a half-life of <12 hours when treated sandy loam soil was flooded with pond water which was aerobically incubated in the dark at approximately 25 °C. Bromoxynil octanoate was 87.64% of the applied at time 0 and declined to undetectable levels by 48 hours posttreatment. The major nonvolatile degradates were bromoxynil (phenol), p-hydroxybenzonitrile, 3-bromo-4-hydroxybenzonitrile, and 3,5-dibromo-4-hydroxybenzoic acid. The degradate bromoxynil (phenol) was 6.59% of the applied immediately posttreatment, 66.47% at 12 hours, 78.77% at 48 hours posttreatment, 39.68% at 168 hours, and 2.39-4.56% at 336 through 720 hours. This data requirement is fulfilled (GLN 162-4; MRID 42364901).

(2) Mobility

Unaged Soil Column Leaching [^{14}C]Bromoxynil Octanoate

Bromoxynil octanoate was mobile in columns of sand, sandy loam, and loam soils that were treated at 228.9 μg/column with phenyl ring-labeled [^{14}C] bromoxynil octanoate and leached with 50.8 cm of a 0.005 M calcium chloride solution. Residues were distributed throughout the length of each soil column and ranged from 2.7-18.2% of the applied in the leachates from the sandy loam-1, sandy loam-2, and loam soil columns; and from 52.4-58.9% in the leachates from the sand soil columns. In the 0-7 cm segment of the columns for sandy loam-1, sandy loam-2 and sand soil, the recoveries were approximately 31-43%, 31-35%, and 13%, respectively. This data requirement is fulfilled (MRID 42271101).

Aged Bromoxynil Octanoate Residues

Aged bromoxynil octanoate (2,6-dibromo-4-cyanophenyl octanoate) residues were not mobile in columns of four soils and an aquatic sediment that were treated with bromoxynil octanoate that had been aerobically aged (aerobic half-lives of 28-100 hours) and then leached with 50.8 cm of a 0.01 M calcium chloride solution. Residues in the sandy loam, loam, clay loam, and aquatic sediment columns were concentrated in the segment composed of the aged soil and the segment immediately beneath it: ^{14}C in the leachates was $\leq$ 0.27% of the applied. Residues in the sand soil columns moved slightly more than in the other soils, but remained concentrated in the upper two segments of the columns (top 10 cm); any ^{14}C-residues in the leachates were [^{14}C]-carbonates and were 3.50-3.58% of the applied. This data requirement is fulfilled (GLN 163-1; MRID 42271101 and 43775001).

Adsorption/Desorption Batch Equilibrium

Bromoxynil octanoate was found to be mobile in sandy loam soil with pH 7.2 and 1.1% organic matter. The Kd was 7.0 (Koc=1,003). The study was considered supplemental and did not satisfy data requirements because the study authors failed to show that the aerobic soil metabolism half-life of the sandy loam soil was much greater than the equilibration time of 24 hours in the batch equilibrium study (163-1; MRID #00116557 and 00114338). However, this data requirement is fulfilled using the aged and unaged column leaching studies (GLN 163-1; MRID 42271101 and 43775001).

Laboratory Volatility and Field Volatility

This data requirement was waived based on the low vapor pressure (1.39×10^{-6} mm Hg) and estimated Henry's Law Constant (9.76×10^{-8} atm-m^3/mol). (GLN 163-2, 163-3; EFGWB # 91-0200-0199, 1/17/91).

(3) Accumulation

Fish Accumulation

[^{14}C]Bromoxynil octanoate residues accumulated in bluegill sunfish continuously exposed to [^{14}C]bromoxynil octanoate at 1.3-4.7 μg/L. The maximum bioconcentration factors were 63x for edible tissue, 400x for inedible tissue, and 230x for whole fish. Depuration occurred with 85-97% of the accumulated residues eliminated by Day 14. This data requirement is fulfilled (GLN 165-4; MRID 42277301-a and 42277301-b).

(4) Field Dissipation

Terrestrial Field Dissipation

Bromoxynil, spray applied at 0.56 kg ai/ha to plots planted in wheat, dissipated with observed half-lives (DT_{50}) of approximately 14 days from a Sorrento silt loam soil in California and 1 day from a Norfolk sandy loam soil in North Carolina. At both sites, bromoxynil octanoate residues were not detected below the 0-15 cm soil depth indicating leaching was not an important route of dissipation. In San Juan Bautista, California, air temperatures ranged from 39^{o} to 96^{o} F and the soil temperatures (10-cm depth) ranged from 55^{o} to 77^{o} F . The field plots in California were irrigated with 30.5 mm of water to supplement the limited rainfall before day 20. In Clayton, North Carolina, air temperatures ranged from 19^{o} to 35^{o} C and soil temperatures (10-cm depth) ranged from 23^{o} to 30^{o} C. Total rainfall during the study was 245 mm; therefore, irrigation was not applied to field plots. Results of a freezer storage stability study indicate there was no significant degradation of either bromoxynil octanoate or bromoxynil (phenol) in the California or North Carolina soils used in the field studies. This data requirement is fulfilled (GLN 164-1; MRID 41653701 and 43071001).

Nitrification Inhibition

Bromoxynil has been shown to inhibit nitrification in soils (Frear, 1976). Nitrification is defined as the oxidation of reduced nitrogen (e.g., ammonium) by bacteria (*Nitrosomonas, Nitrobacter* species) to nitrate through the intermediate product, nitrite (Brady and Weil, 1996). Various environmental factors such as soil reaction (acidity and alkalinity), aeration, moisture, carbon sources, temperature and nutrient availability influence the nitrification process. For certain environmental conditions, commercially-available nitrification inhibitors (*Dwell®*, *N-Serve®*) are used in production agriculture to temporarily slow conversion of ammonium fertilizers to nitrate because nitrate can be lost through

leaching or denitrification. In the environment, adaptation to nitrification inhibitors, such as bromoxynil, is demonstrated by the increasing bromoxynil concentrations that are needed to cause 50% inhibition (Frear, 1976). In addition, these adaptation studies support the observation that microbial-mediated metabolism (aerobic soil metabolism half-lives of 31-51 hours; field dissipation half-life of 1-14 days) is an important process for degradation of bromoxynil in soils; therefore, nitrification inhibition would generally occur only on a temporary basis. Thus, nitrification inhibition by bromoxynil does not appear to be a concern.

(5) Spray Drift

No specific spray drift studies for bromoxynil were reviewed. Droplet size spectrum (201-1) and drift field evaluation (202-1) studies were required since the different products may be applied by aircraft and because of a concern for potential risk to nontarget aquatic organisms. However, to satisfy these requirements the registrant in conjunction with other registrants of other pesticide active ingredients formed the Spray Drift Task Force (SDTF). The SDTF has completed and submitted to the Agency its series of studies which are intended to characterize spray droplet drift potential due to various factors, including application methods, application equipment, meteorological conditions, crop geometry, and droplet characteristics. In the near future, EPA plans completion of its evaluation of these studies. In the interim and for this assessment of bromoxynil, the Agency is relying on previously submitted spray drift data and the open literature for off-target drift rates. The rates are 1% of the applied spray volume from ground applications and 5% from aerial applications at 100 feet downwind. After its review of the new studies the Agency will determine whether a reassessment of the potential risks to nontarget organisms is warranted.

c. Water Resources

(1) Ground Water

The Office of Pesticide Programs (OPP) evaluates the persistence and mobility of each pesticide for ground water concerns. If the data indicate that the parent and/or degradates are persistent and mobile, then a small-scale prospective ground water study may be requested. The basic triggering criteria include: 1) weight of the evidence from laboratory and field dissipation studies indicating that the pesticide has properties and characteristics similar to pesticides that are known to leach or have been detected in ground water; 2) movement of the parent or degradates 75-90 centimeters through the soil profile or plow layer in a field dissipation study; 3) reports of detections in ground water from other monitoring studies; and 4) information about toxicity. In addition, use patterns, application rates, timing of application, potential acreage treated, depth to ground water, soil types, hydraulic gradient, and climate are also evaluated as part of the triggering criteria.

Persistence, mobility and detections in ground water are used also to evaluate a chemical to determine whether its use should be restricted. A pesticide may be recommended as a candidate for restriction if it exceeds one or more criteria for each of the three factors (persistence, mobility, and detections).

Persistence and Mobility

Bromoxynil octanoate was evaluated for persistence and mobility in relation to its potential to leach to ground water. Bromoxynil octanoate is not considered a candidate for restricted use due to ground water concerns. Below is a summary of that evaluation. This table does not include degradate data.

Table 34: Mobility and Persistence of Bromoxynil Octanoate Relative to Restricted Use Criteria

Factor	Characteristic	Restricted Use Criteria	Reported Value(s)
Persistence	Field dissipation half-life	> 3 weeks or	14 days
	Lab-derived aerobic soil metabolism half-life	> 3 weeks or	2 days
	Hydrolysis half-life	< 10% in 30 days or	calculated 44%,130%,882% pH 5,7,9, respectively
	Photolysis half-life (soil)	< 10% in 30 days and	calculated 326%
	Soil adsorption: K_d	< 5 ml/g or	7.0 ml/g
Mobility	Soil adsorption: K_{oc}	< 500 ml/g or	1,003 ml/g
	Depth of leaching in field dissipation study	75 - 90 cm	not below 15 cm

Ground Water Detections

Limited monitoring information for bromoxynil octanoate in ground water is available. The "Pesticides in Ground Water Database" (EPA,1992) reports sampling for bromoxynil (no distinction made between esters and the phenolic compound) in 107 wells in four counties in Oregon between 1985 and 1987. The wells sampled in each area (public water supply and domestic) were selected based on suspected vulnerability, susceptibility to contamination, and availability of information on well construction and depth. No information on the details of the monitoring was available. No detections of bromoxynil octanoate were reported. Below is a summary of that evaluation.

Table 35: Detections of Bromoxynil Octanoate Relative to Restricted Use Criteria

Criterion	Characteristic	Restricted Use Criteria	Reported Detections
Detections	Number of wells per state with detections	25 wells in 4 or more states or	No Detections
	Number of counties with detections > 10% of reference point	3 counties at >10% of MCL or HAL	No MCL or HA Established; Calculated HA from Reference Dose 11 μg/L

Ground-Water Concerns

Based on the available data, the Agency concludes that the potential for ground water contamination from bromoxynil octanoate is low; it does not exhibit the mobility or persistence characteristics of pesticides that are normally found in ground water. Although bromoxynil octanoate has been found to be mobile under certain conditions (sand, sandy loam, and loam soils as reported in the acceptable unaged column leaching study), it dissipates in the environment by abiotic hydrolysis, photodegradation and microbially-mediated metabolism.

Since bromoxynil octanoate readily degrades to bromoxynil (phenol) via hydrolysis (half-life 2-34 days), the mobility and persistence of the phenol were examined also. Bromoxynil (phenol) is an anion in environmentally significant pH ranges, has a water solubility of 130 ppm, and is stable to hydrolysis at pH 5, 7 and 9. Batch equilibrium and soil column leaching studies indicate that bromoxynil (phenol) is mobile in sandy soils with low organic matter content (Kd 1.4; 1.3% OM). If heavy rainfall occurred to a sandy soil with low organic matter content, bromoxynil (phenol) could potentially leach to ground water. However, based on the aerobic soil metabolism study, bromoxynil (phenol) degrades very rapidly to CO_2 (33.6% of the applied), and to the non-volatile degradates 3,5-dibromo-4-hydroxybenzamide (which decreased from 21.6% to 0.3% by day 28), and 3,5-dibromo-4-hydroxybenzoic acid (which decreased from 34.8% to 0.4% by day 28). Also, based on the anaerobic aquatic metabolism study, bromoxynil (phenol) degrades under anaerobic conditions (levels were 3.6% after 8 weeks). Therefore, although bromoxynil (phenol) has the potential to leach to ground water under certain conditions, its rapid aerobic and anaerobic degradation reduces the likelihood of ground water contamination. The Agency does not consider bromoxynil (phenol) to be a candidate for restricted use due to ground water concerns. The potential for ground water contamination from bromoxynil (phenol) is low.

Status of Ground Water Monitoring Requirements

The small-scale prospective (GLN 166-1) and the small-scale retrospective (GLN 166-2) ground water monitoring studies were reserved pending preliminary assessment of potential for leaching to

ground water based upon the results of laboratory and terrestrial field dissipation studies. The (166-3) large-scale retrospective ground water monitoring study was reserved pending the review of the results from the small-scale retrospective ground water monitoring study. Based on the results from the laboratory and terrestrial field dissipation studies, bromoxynil octanoate does not have the mobility or persistence characteristics of pesticides that are normally found in ground water. Therefore, no ground water monitoring studies are required for bromoxynil octanoate at this time.

(2) Surface Water

Information from environmental fate studies indicates that bromoxynil octanoate should not persist in surface waters. Based on the aerobic aquatic and anaerobic aquatic metabolism studies, bromoxynil octanoate degrades quickly to the phenolic compound (which further degrades to approximately 2% of the applied) with a half-life of <12 hours and 3.7 days, respectively. Laboratory studies indicate that photolytic degradation occurs rapidly with a half-life of 4.6 days. In aquatic systems abiotic hydrolysis of bromoxynil octanoate is base-catalyzed with the major degradate being bromoxynil (phenol). Reported hydrolysis half-lives were 34.1, 11.5 and 1.7 days at pH 5, 7 and 9.

The reported vapor pressure (1.39×10^{-6} mm Hg) and the Henry's constant (9.76×10^{-8} atm m^3/mol) indicate that bromoxynil octanoate should not readily volatilize from surface water environments. Based on the Freundlich adsorption coefficient (K_d =7.0 ml/g) from a supplemental study, bromoxynil octanoate might be transported in surface runoff waters. However, bromoxynil octanoate is not predicted to persist in surface waters.

Estimated Aquatic Concentrations Tier 1: Tier 1 Estimated Environmental Concentrations (EECs) were calculated for bromoxynil octanoate application to a variety of crops at several different rates and using several application patterns. These EECs, calculated using the GENeric Estimated Environmental Concentration Program (GENEEC), represent a screen and depend on basic chemical parameters and pesticide label application information. GENEEC uses a chemical's soil/water partition coefficient and degradation half-life values to estimate runoff from a ten hectare field into a one hectare by two meter deep pond. It was designed to specifically model runoff from agricultural fields. GENEEC uses application information for each crop, but uses the same site for all applications. The site is in Yazoo, Mississippi and has a Loring silt loam soil.

GENEEC calculates both acute and chronic generic EEC values. It considers reduction in dissolved pesticide concentration due to adsorption of pesticide to soil or sediment, incorporation, degradation in soil before washoff to a water body, direct deposition of spray drift into the water body,

and degradation of the pesticide within the water body. Because the review of the Spray Drift Task Force data has not been completed, spray drift is assumed to be 1% of the application rate for ground applications and 5% of the application rate for aerial applications.

The following values were used for input into the GENEEC program:

Soil organic carbon partitioning coefficient:	1003
Soil aerobic metabolic half-life	2 days
Aqueous photolysis half-life:	4.6 days
Aerobic aquatic metabolism half-life:	1 day
Water solubility:	0.08 ppm

Table 36 : Generic EECs for bromoxynil octanoate

Crop	Application Method	Application Rate in lbs a.i./A (number of apps.)	Peak EEC (ppb)	4-day EEC (ppb)	21-day EEC (ppb)	56-day EEC (ppb)
Corn, Small Grains	Broadcast - ground & aerial	0.5 (1) maximum rate	4.5	2.2	0.4	0.15
Corn	Broadcast- ground & aerial	0.28 (1) typical rate	2.6	1.2	0.3	0.15
Small Grains	Broadcast - ground & aerial	0.31 (1) typical rate	3.0	1.3	0.3	0.15
Cotton	Broadcast- ground	0.5 (**3**) maximum rate - 10 day application interval	9.4	4.5	0.9	0.3
Cotton	Broadcast - ground	0.4 (2) typical rate - 10 day application interval	8.0	3.8	0.7	0.3
Cotton	Aerial	0.5 (**3**) maximum rate - 10 day application interval	10.0	5.0	1.0	0.4
Cotton	Aerial	0.4 (2) typical rate - 10 day application interval	8.4	4.1	0.9	0.3

Peak exposure levels range from 2.6 to 10.0 ppb (μg/L), with 21-day average values ranging from 0.3 to 1.0 ppb (μg/L), and, 56-day average values ranging from 0.15 to 0.4 ppb (μg/L). For a single ground application applied at 0.5 lb ai/A, the peak EEC was 4.5 ppb for both corn and small grains. The peak EEC for corn and small grains decreased with the typical use rates of 0.31 and 0.28 lb ai/A, respectively. The EEC for cotton was estimated using three applications with a ten day interval at a maximum application rate of 0.5 lb ai/A. The peak EEC was 9.4 and 10.0 ppb for ground and aerial applications, respectively. Using a typical application rate of 0.4 lb ai/A, the peak EEC decreased for both the ground and aerial applications.

The preceding EECs were used to assess the risk of bromoxynil octanoate to nontarget aquatic organisms. They were compared to ecotoxicity information for bromoxynil octanoate in the risk assessment portion of this document (Section 3(2)).

Estimated Aquatic Concentrations (Tier 2) for Drinking Water Exposure and Human Health Assessment: Bromoxynil octanoate rapidly degrades to bromoxynil, therefore all calculations have been performed for bromoxynil, rather than for bromoxynil octanoate. The purpose of this analysis was to generate aquatic exposure estimates for use in the human health risk assessment for bromoxynil. These Tier 2 EECs were also used to further refine the ecological risk of bromoxynil octanoate application to cotton.

A Tier 2 EEC uses a single site which represents a high exposure scenario for the use of the pesticide on a particular crop or non-crop use site. The weather and agricultural practice are simulated at the site over multiple (in this case, 20) years so that the probability of an EEC occurring at that site can be estimated. EEC's were calculated for the Buctril 2EC (Registration Number 264-540) formulation because this was the formulation being registered for use on cotton.

The Tier 2 EEC's generated in this analysis were calculated using PRZM 2.3 for simulating the agricultural field and EXAMS 2 for fate and transport in surface water. Spray drift was simulated using an assumption that 5% of applied bromoxynil reached surface water at the time of application and that 75% of the chemical was deposited on site. The other 20% is assumed to either remained airborne or be deposited on the ground beyond the pond.

The scenario chosen was a cotton field in Yazoo, Mississippi. The scenario was chosen to represent a site that was expected to produce more runoff than 90% of the sites used for cotton. The simulation was made with the maximum application rate of 0.5 $lb \cdot acre^{-1}$ with the maximum number of yearly applications, three. The interval between applications was 14 days. The Tier 2 upper tenth percentile EEC's for cotton are listed in Table 37. The EEC's have been calculated so that in any given year, there is a 10% probability that the maximum average concentration of that duration in that year will equal or exceed the EEC at the site.

Table 37: Tier 2 Upper Tenth Percentile EEC's for Bromoxynil Octanoate (as Bromoxynil) on Cotton

Maximum	4 Day	21 Day	60 Day	90 Day	Long-term Mean*
12.3 $\mu g \cdot L^{-1}$	10.0 $\mu g \cdot L^{-1}$	5.3 $\mu g \cdot L^{-1}$	2.5 $\mu g \cdot L^{-1}$	1.6 $\mu g \cdot L^{-1}$	0.24 $\mu g \cdot L^{-1}$

*Upper 90% confidence bound on the 20 year mean with the variance calculated from the annual means.

Limitations of this analysis for drinking water exposure estimates: There are certain limitations imposed when Tier 2 EEC's are used for drinking water exposure estimates. A single 10 hectare field with a 1 hectare pond does not accurately reflect the dynamics in a watershed large enough to support a drinking water facility. A basin of this size would certainly not be planted completely to a single crop nor be completely treated with a pesticide. Additionally, treatment with the pesticide would likely occur over several days or weeks, rather than all on a single day. This would reduce the magnitude of the concentration peaks, but also make them broader, reducing the acute exposure but perhaps increasing the chronic exposure. The fact that the simulated pond has no outlet is also a limitation as water bodies in this size range would have at least some flow through (rivers) or turnover (reservoirs). In spite of these limitations, a Tier 2 EEC can provide a reasonable upper bound on the concentration found in surface water if not an accurate assessment of the real concentration. Risk assessment using Tier 2 values can capably be used as refined screens to demonstrate that the risk is below the level of concern.

Characterization of Surface Water Monitoring Data for Bromoxynil

This section summarizes the water resource monitoring data for bromoxynil collected by the USGS National Water Quality Assessment (NAWQA) Program from 1993-1995. Comparisons between the surface water modeling results (Tiers 1 and 2) and the USGS monitoring data suggest reasonable agreement for estimating surface water environmental concentrations using either data source. However, the agreement between modeling results and monitoring data would not be expected based on the variation in hydrologic settings. Table 38 shows the maximum and long-term mean values from Tier 1 and 2 modeling compared to the USGS NAWQA maximum, mean and median values.

Table 38: Modeling and Monitoring Data for Bromoxynil in Surface Waters

Data Source	Maximum Concentration (µg/L)	Annual Mean (µg/L)
Tier 1 Modeling	6.9	Not estimated
Tier 2 Modeling	12.3	0.24
USGS Monitoring	6.1	0.105 (median; all data) 0.53 (mean; all data) 0.60 (median; data > 0.2 µg/L)

Note: "all data" indicates results (n = 20) reported as "detects" by the USGS; "non-detects" were not included.

Bromoxynil water resource monitoring data from the USGS NAWQA Program were reported during the 1993-1995 period from 7 of the 20 river basins (termed "Study Units" by the USGS) throughout the U.S. The NAWQA Program examined drainage basins that were primarily agricultural land use. The percentage of detections was 1.1% from a total of 1,925 surface water samples (minimum reporting limit = 0.035 µg/L). Analysis of the 20 detections $\geq$0.03 µg/L yielded a median

value of 0.105 µg/L with a mean of 0.53 µg/L (Table 38). The maximum concentration of 6.1 µg/L was measured at the Lonetree Creek location in the South Platte River Study Unit, CO. For reported concentrations above 0.2 µg/L (range of 0.45-6.1 µg/L), the median value was 0.60 µg/L. Geographically, the highest concentrations were reported for samples collected in Colorado, Indiana, Nebraska and Washington. For urban land use, bromoxynil was not detected in surface waters, and one detection in groundwater (0.07 µg/L) was reported from a total of 2,245 samples. Specific information on application of bromoxynil in each of the Study Units was not available for this evaluation.

The following table provides detected concentrations of bromoxynil in surface water - USGS NAWQA data (1993-1995):

Table 39: Bromoxynil Detections in Surface Waters - USGS NAWQA (1993-1995)

Study Unit	Location	Date	Concentration (µg/L)
South Platte, CO	Lonetree Creek	06/29/94	6.1
		05/11/94	0.93
		06/30/93	0.45
		07/12/94	0.10
		05/25/94	0.09
White River, IN	Kessinger Ditch	06/29/93	0.77
	Clifty Creek	06/16/94	0.06
Red River - North (ND/MN)	Red River	07/06/95	0.25
	Snake River	06/16/94	0.12
		06/20/94	0.10
Central Nebraska	Prairie Creek	07/28/94	0.08
	Shell Creek	06/29/93	0.55
Columbia Plateau, WA	EL 68D Wasteway	05/16/94	0.09
		05/04/94	0.02
		05/25/93	0.02
	Palouse River	04/27/93	0.60
		05/05/93	0.13
Willamette Valley, OR	Zollner Creek	10/28/94	0.11
	Pudding River	04/14/95	0.03
Trinity River	not listed	06/07/95	0.05

NOTE: The minimum reporting limit (0.035 µg/L) equals the method detection limit calculated with the U.S.EPA method (1992). For bromoxynil in surface waters, the instrument detection limit (single operator) was 0.011 µg/L with a mean accuracy (percent of the true concentration) of 52% and a relative standard deviation (RSD) of 7%.

Surface water monitoring of the South Platte River Study Unit at the Lonetree Creek Basin displayed the highest and most frequent detectable levels of bromoxynil. Land use information for this basin indicates irrigated agriculture is predominant in the lower portion of the basin near the sampling station (Kimbrough and Litke, 1996). The contributing drainage area for the study was estimated to be 202 square kilometers. Precipitation in the basin is approximately 40 cm/year (about 16 inches/year) and occurs primarily as infrequent, high-intensity storm events such as summer thunderstorms. Information describing the representativeness of the Lonetree Creek Basin to other surface water basins where bromoxynil was applied is not currently known.

Monitoring results from the NAWQA Program represent high quality data. All aspects of the program were carefully designed to obtain monitoring data for surface and ground waters from diffuse (non-point) sources. However, several limitations and uncertainties should be considered before using the USGS monitoring data to estimate surface water concentrations for human health risk assessment. The NAWQA data were not specifically collected to assess water quality at drinking-water supply intakes; however, some sampling locations may be representative of source waters in certain areas. It is important to note the laboratory recoveries were approximately 50%; therefore, the measured values may be roughly one-half of the actual water concentrations. For bromoxynil in surface waters, the low laboratory recoveries did not vary considerably from the 50% recovery level as shown by the relative standard deviation (RSD) of 7% (USGS Open-File Report 96-216). The samples for the NAWQA monitoring program were collected from single locations at varying sampling dates and analyzed by a multi-analyte method. Differences in stream flow levels among the various sampling locations could significantly influence environmental concentrations, therefore, it might be more appropriate to evaluate monitoring results reported as "flow-weighted concentrations". Monitoring data were not available for surface water reservoirs, lakes and estuaries.

Comparison of the Tier 1 (GENEEC) and Tier 2 (PRZM-EXAMS) estimated environmental concentrations (EECs) with the USGS NAWQA monitoring data suggests reasonable agreement among the various data sources. If the maximum USGS value is multiplied by 2 (approximate "correction" for 50% laboratory recovery), the result of $\approx$12 µg/L shows good agreement with the maximum Tier 2 EEC. It is unclear why surface water modeling results using a "static pond" hydrologic scenario are relatively close to the stream and river hydrologic systems monitored by the USGS.

The bromoxynil surface water protocol drafted in response to the cotton registration decision outlines the monitoring procedure to track the potential movement of bromoxynil from field application sites through surface water resources for evaluating potential impact to surface water drinking water utilities. This monitoring program is discussed in three phases: 1) survey of surface water drinking

water utilities, 2) potential impact to surface drinking water utilities at the watershed scale, and 3) intensive, field-scale surface runoff and watershed studies with edge-of-field monitoring. These three phases should be conducted concurrently in an attempt to gain a more complete picture of the monitored compound in surface waters. The pesticide levels at drinking water utilities will be considered in the water exposure assessment component of dietary risk assessments as required in FQPA. The field runoff studies are required to document the source(s), extent and magnitude of pesticide residues which may be transported via surface runoff and spray drift.

For the bromoxynil surface water monitoring study, the study locations must cover the range for the major agricultural uses (principally corn, cotton and small grains). Since bromoxynil degrades relatively rapidly (DT_{50} <14 days), both the field scale and basin scale monitoring will require intensive sampling during the period of time from application through several half-lives of the compound. There are no degradates of concern with this compound, therefore, only parent compound will be monitored. Also, since bromoxynil does not bioaccumulate in tissues or bind to sediments, biota or sediment samples are not required at this time.

To estimate a reasonable high end exposure, EPA focused on the calculated time weighted annual mean concentrations of bromoxynil at each of 11 USGS monitoring sites, which the EPA views as located in watersheds likely to have bromoxynil use. (These values were not corrected for the analytical recovery rate of 50%.) These time weighted annual mean concentrations ranged from 0.011 ppb to 0.18 ppb, with 10 out of the 11 sites with time weighted annual mean concentrations below 0.05 ppb. Six of the 10 sites had time weighted annual mean concentrations at or below 0.014 ppb. The highest annual time-weighted mean (0.18 ppb) was located in a relatively small watershed (approximately 100 square miles) and a relatively small water body, and the calculated annual mean value at this site was significantly influenced by the presence of a single high value (the highest value found in all of the available monitoring data). Based on this information, EPA believes that 0.05 ppb is a reasonable high end estimate for purposes of estimating drinking water exposure.

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

Explanation of the Risk Quotient (RQ) and the Level of Concern (LOC): The Levels of Concern are criteria used to indicate potential risk to nontarget organisms. The criteria indicate that a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. There are two general categories of LOC (acute and chronic) for each of the four nontarget faunal groups and one category (acute) for each of two nontarget floral groups. In order to determine

if an LOC has been exceeded, a risk quotient must be derived and compared to the LOC's. A risk quotient (RQ) is calculated by dividing an appropriate exposure estimate (e.g., the estimated environmental concentration (EEC)), by an appropriate toxicity test effect level (e.g., the LC_{50}). The acute effect levels are:

-EC_{25} (terrestrial plants),
-EC_{50} (aquatic plants and invertebrates),
-LC_{50} (fish and birds), and
-LD_{50} (birds and mammals)

The chronic test results are the:

-NOEL (sometimes referred to as the NOEC) for avian and mammal reproduction studies, and either the NOEL for chronic aquatic studies, or the Maximum Allowable Toxicant Concentration (MATC) which is the geometric mean of the NOEL and the LOEL (sometimes referred to as the LOEC) for chronic aquatic studies.

When the risk quotient exceeds the LOC for a particular category, risk to that particular category is presumed to exist. Risk presumptions are presented along with the corresponding LOC's.

Levels of Concern (LOC) and Associated Risk Presumption

Mammals, Birds

IF THE	LOC	PRESUMPTION
acute RQ>	0.5	Potentially high acute risk
acute RQ>	0.2	Risk that may be mitigated through restricted use
acute RQ>	0.1	Endangered species may be affected acutely
chronic RQ>	1	Chronic risk, endangered species may be affected chronically

Fish, Aquatic invertebrates

IF THE	LOC	PRESUMPTION
acute RQ>	0.5	Potentially high acute risk
acute RQ>	0.1	Risk that may be mitigated through restricted use

acute RQ>	0.05	Endangered species may be affected acutely
chronic RQ>	1	Chronic risk, endangered species may be affected chronically

Plants

IF THE	LOC	PRESUMPTION
RQ>	1	Potentially high risk
RQ (using the NOEC or EC05)	> 1	Endangered plants may be affected

Currently, there are no separate criteria for restricted use or chronic effects for plants.

Bromoxynil octanoate use patterns addressed in risk assessment: Bromoxynil octanoate is used on a wide variety of agricultural crops such as corn and small grains (oats, wheat, barley).

Terrestrial Animals and Terrestrial and Semi-aquatic Plants: The majority of use sites have a maximum use rate of 0.5 lbs ai/A or less (there are no uses with a higher application rate). This includes such sites as corn, cotton, and small grains. These use sites make up over 90% of bromoxynil octanoate usage based on pounds applied annually. Bromoxynil octanoate is registered on a variety of other sites, all of which are less than 3% of the annual pounds applied (garlic/onions 1%, sorghum 2%, and alfalfa 1%). The typical use rates of 0.4 lbs ai/A for cotton, 0.28 lbs ai/A for corn, and 0.31 lbs ai/A for small grains were also used to calculate EECs.

Aquatic Animals and Plants: Aquatic EECs were calculated using GENEEC for the several use rates and patterns [see EEC section].

The application rates for the minor uses of bromoxynil octanoate (including alfalfa, flax, mint, and turf) were not used to estimate EECs because they are lower than those for the major crops. As a result, exposure from these use patterns would not be higher than exposure from other uses where GENEEC was used to estimate exposure.

(1) Exposure and Risk to Nontarget Terrestrial Animals

(a) Birds

Residues expected on dietary food items following application are compared to LC_{50} values to predict hazard to birds. Day 0 residues on vegetation were estimated based on the work of Hoerger

and Kenaga (1972) as modified by Fletcher et al. (1994) for a maximum application rate of 0.5 lbs and the typical application rate of 0.4 lb ai/A.

For cotton (0.5 lb ai/A), the highest (peak) residues after the third application were estimated using a computerized dissipation program that uses first-order dissipation kinetics at an assumed rate to calculate daily estimated residues after repeated applications. The use rate per application is 0.5 lb ai/A with a between application interval of 10 days, during which time the residues from the previous applications would partially degrade. A half-life of 7 days was used to estimate the degradation of bromoxynil octanoate on vegetation. This half-life was chosen based on the hydrolysis, aerobic soil metabolism, and terrestrial field dissipation half-lives. This value is consistent with the estimated half-lives for other pesticides (Willis and McDowell, 1987).

Risk from bromoxynil octanoate at typical use rates is not greater than the risk at the higher application rates; therefore, RQs were not calculated for these rates. The predicted 0 day maximum residues of bromoxynil octanoate that are expected to occur on different avian food items following the two highest applications, and their corresponding acute risk quotients, are presented in the table below:

Table 40: Maximum Estimated Environmental Concentrations and Acute Dietary Risk Quotients for Birds*

Food items	Appl. Rate (lbs ai/A)	No. of Aplications	EEC (ppm)	RQ
Short Grasses	0.4	1	139	0.12
	0.5		174	0.15
	0.4	2	209	0.15
	0.5	3	261	0.3
Long Grasses	0.4	1	64	0.06
	0.5		80	0.07
	0.4	2	96	0.09
	0.5	3	120	0.01
Broadleaf Plants and insects	0.4	1	78	0.07
	0.5		99	0.08
	0.4	2	117	0.1
	0.5	3	148	0.12
Fruits and pods	0.4	1	9	0.007
	0.5		12	0.01
	0.4	2	13	0.01
	0.5	3	17	0.01

* Based on an LC_{50} = 1,150 ppm

The LOC for endangered species (0.1) has been slightly exceeded for all modeled use rates on short grasses; both single and multiple applications; and on broadleaf plants and insects. Therefore, a may effect for endangered birds has been identified. The risk quotients at the maximum use rate for cotton assuming three applications, exceed the restricted use LOC (0.2) by a small margin on short

grasses. However, the use of bromoxynil octanoate is expected to pose minimal overall acute risk to avian species, as further described in Section b., Environmental Risk Characterization. Maximum residues and their corresponding chronic risk quotients are presented in the table below.

Table 41: Maximum Estimated Environmental Concentrations and Chronic Dietary Risk Quotients for Birds*

Food items	Appl. Rate (lbs ai/A)	No. Of Applications	EEC (ppm)	RQ
Short Grasses	0.4	1	139	1.5
	0.5		174	1.5
	0.4	2	209	1.5
	0.5	3	261	3
Long Grasses	0.4	1	64	0.6
	0.5		80	0.7
	0.4	2	96	0.9
	0.5	3	120	1.2
Broadleaf Plants and insects	0.4	1	78	0.7
	0.5		99	1
	0.4	2	117	1.16
	0.5	3	148	1.5
Fruits and pods	0.4	1	9	0.09
	0.5		12	0.12
	0.4	2	13	0.13
	0.5	3	17	0.15

* Based on an NOEL = 102 ppm

For both single and multiple applications, the chronic LOC (1) for endangered and nonendangered species has been exceeded by a small margin for the two highest use rates on short grasses and on broadleaf plants and insects. Therefore, a chronic may effect for endangered birds has been identified. However, the use of bromoxynil octanoate is expected to pose minimal overall chronic risk to avian species, as further described in Section b., Environmental Risk Characterization.

(b) Mammals

Mammals are assumed to be exposed to dietary residues similar to birds. The EEC's calculated for avian species will be used to estimate exposure to mammals.

Acute Risk

Acute hazard to small mammals was addressed using the acute oral LD_{50} value for the rat converted to an estimated LC_{50} value for dietary exposure. The estimated LC_{50} was derived using the following formula:

$LC_{50} = LD_{50}$ x body weight (g) / food consumed per day (g)

Acute risk to mammals was assessed by calculating RQs for three representative species: the meadow vole, the field mouse, and the least shrew. Estimated mammalian LC_{50} values for these three species of small mammals are presented below:

Table 42: Estimated Small Mammal Dietary Exposure (Based on an LD_{50} = 238 mg/kg)

Small Mammal	Body Weight (g)	Percent of Weight Eaten Per Day	Food Consumed Per Day (g)	Estimated LC_{50} (ppm)
Meadow vole	46	61 %	28.1	390
Adult field mouse	13	16 %	2.1	1473
Least shrew	5	110 %	5.5	216

The above table is based on information contained in Principles of Mammalogy by D. E. Davis and F. Golly, published by Reinhold Corporation, 1963.

The risk quotients are calculated by dividing the EECs (i.e. residues) by the estimated LC_{50}'s. The table below shows the risk quotients for peak exposures of bromoxynil.

Table 43: Mammalian Acute Risk Quotients

Species and Diet	Application Rate (lb ai/A)	Maximum EEC[1] in Food Item (ppm)	Acute Risk Quotient
Meadow vole consuming short grasses	0.5 (single app)	174	0.16
	0.4	139	0.13
	0.4 (two apps)	209	0.19
	0.5 (three apps)	261	0.24
Adult field mouse consuming seeds	0.5 (single app)	12	0.01
	0.4 (single app)	9	0.01
	0.4 (two apps)	13	0.02
	0.5 (three apps)	17	0.02
Least shrew consuming insects	0.5 (single app)	99	0.09
	0.4 (single app)	78	0.07
	0.4 (two apps)	117	0.11
	0.5 (three apps)	148	0.13

[1]Based on Hoeger and Kenaga (1972) with modifications by Fletcher et al. (1994).

For the modeled use rates (0.4 and 0.5, with two and three applications, respectively), the LOC for presumption of risk (0.5) has been exceeded for the meadow vole and the least shrew. The LOC for

risk that may be mitigated through restricted use (0.2) classification has also been exceeded for these use rates for the vole and the least shrew. The LOC for presumption of risk to endangered species (0.1) has been exceeded for these use rates for the vole, the field mouse, and the least shrew. This indicates that the use of bromoxynil at these rates poses an acute risk to mammals, both endangered and non-endangered. However, the acute risk to mammals, including threatened and endangered species is expected to be low, as further described in Section b., Environmental Risk Characterization.

Chronic Risk

Risk quotients were calculated for chronic effects of bromoxynil to mammals. Although rat reproductive studies revealed little reproductive effects, bromoxynil has been shown to be a developmental toxicant. Therefore, in order to assess chronic affects to mammals, results from a developmental toxicity study will be used (NOEC = 50 ppm). The maximum EEC's and chronic risk quotients are shown in the table below.

Table 44: Mammalian Chronic Risk Quotients (Based on a Rat NOEL=50 ppm[2])

Application rate	Food item	Maximum EEC (ppm)	Chronic Risk Quotient
0.5 (single appl.)	Short grasses	174	3.5
	Long grasses	80	1.6
	Broadleaf plants and insects	99	2.0
	Fruits and pods	12	0.2
0.4 (single appl.)	Short grasses	140	2.8
	Long grasses	64	1.3
	Broadleaf plants and insects	78	1.6
	Fruits and pods	9	0.2
0.4 (two appl.)	Short grasses	209	4.2
	Long grasses	96	1.9
	Broadleaf plants and insects	117	2.3
	Fruits and pods	13	0.3
0.5 (three appl.)	Short grasses	261	5.2
	Long grasses	120	2.4
	Broadleaf plants and insects	148	3.0
	Fruits and pods	17	0.3

[1]Based on Hoeger and Kenaga (1972) with modifications by Fletcher et al. (1994).

[2] MRID 41149301, rat reproduction study for phenol. NOEL of 4 mg/kg/day (50 ppm) is based on decreased body weight gain of offspring.

All of the chronic RQs on all food items except fruits and pods exceed the LOC of 1 for all use rates. These results indicate that all use rates of bromoxynil pose a risk of causing chronic effects to

mammals and may cause chronic adverse effects to threatened and endangered species of mammals. The chronic risk to mammals is developmental and reproductive. It is, however, uncertain whether or not they would be exposed to high enough residues to cause chronic effects, as further described in Section b. of the Environmental Risk Characterization.

(c) Insects

Bromoxynil (technical grade) is practically non-toxic to honeybees. Therefore, minimal risk to honeybees is presumed.

(2) Exposure and Risk to Nontarget Aquatic Animals

(a) Freshwater Fish

Acute

The table below shows the EEC's, from GENEEC, and acute risk quotients for freshwater fish.

Table 45: Acute risk quotients for freshwater fish (Species LC_{50} for bluegill sunfish = 53 ppb and channel catfish = 23 ppb)

Crop	Application Method	Application Rate in lbs a.i./A (number of apps.)	Peak EEC (ppb)	Acute RQ	
				Sunfish	Catfish
Corn, Small Grains	Broadcast - ground & aerial	0.5 (1) maximum rate	4.5	0.08	0.20
Corn	Broadcast- ground & aerial	0.28 (1) typical rate	2.6	0.05	0.11
Small Grains	Broadcast - ground & aerial	0.31 (1) typical rate	3.0	0.02	0.13
Cotton	Broadcast- ground	0.5 (3) maximum rate - 10 day application interval	9.4	0.18	0.4
Cotton	Broadcast - ground	0.4 (2) typical rate - 10 day application interval	8.0	0.15	0.3
Cotton	Aerial	0.5 (3) maximum rate - 10 day application interval	10.0	0.19	0.4
Cotton	Aerial	0.4 (2) typical rate - 10 day application interval	8.4	0.16	0.4

Risk quotients for both the rainbow trout and the channel catfish were calculated to estimate risk to freshwater species. In this case, the catfish was more sensitive to bromoxynil octanoate. The catfish is also considered representative of species that would inhabit waters near cotton fields.

Bromoxynil octanoate, when applied to cotton, corn, and small grains, at both the maximum and typical application rates, slightly exceeds the LOC (0.05) for endangered species and the LOC (0.1) for risk that may be mitigated through restricted use. Therefore, applications of bromoxynil octanoate at these rates may affect endangered freshwater fish species.

Chronic

The table below shows the EEC's, from GENEEC, and risk quotients for freshwater fish.

Table 46: Chronic risk quotients for freshwater fish (Species MATC = 12 ppb for fathead minnow)

Crop	Application Method	Application Rate in lbs a.i./A (number of apps.)	56 day EEC ppb	Chronic RQ
Corn, Small Grains	Broadcast - ground & aerial	0.5 (1) maximum rate	0.15	0.01
Corn	Broadcast- ground	0.28 (1) typical rate	0.15	0.01
Small Grains	Broadcast - ground	0.31 (1) typical rate	0.15	0.01
Cotton	Broadcast- ground	0.5 (3) maximum rate - 10 day application interval	0.3	0.03
Cotton	Broadcast - ground	0.4 (2) typical rate - 10 day application interval	0.3	0.03
Cotton	Aerial	0.5 (**3**) maximum rate - 10 day application interval	0.4	0.04
Cotton	Aerial	0.4 (2) typical rate - 10 day application interval	0.3	0.03

Based on the MATC from the fathead minnow early life stage study (12 ppb) and the 56-day average GEECs, no LOCs are exceeded. Therefore, all use sites represent minimal chronic risk to fish.

(b) Freshwater Invertebrates

Acute

The table below shows the EEC's, from GENEEC, and acute risk quotients for freshwater invertebrates.

Table 47: Acute risk quotients for freshwater invertebrates (Species EC_{50} = 11 ppb for the *Daphnia pulex*)

Crop	Application Method	ApplicationRate in lbs a.i./A (number of apps.)	Peak EEC (ppb)	Acute RQ
Corn, Small Grains	Broadcast - ground	0.5 (1) maximum rate	4.5	0.4
Corn	Broadcast- ground	0.28 (1) typical rate	2.6	0.3
Small Grains	Broadcast - ground	0.31 (1) typical rate	3.0	0.3
Cotton	Broadcast- ground	0.5 (3) maximum rate - 10 day application interval	9.4	0.9
Cotton	Broadcast - ground	0.4 (2) typical rate - 10 day application interval	8.0	0.7
Cotton	Aerial	0.5 (3) maximum rate - 10 day application interval	10.0	0.9
Cotton	Aerial	0.4 (2) typical rate - 10 day application interval	8.4	0.7

Treating corn and small grains with bromoxynil octanoate using either aerial or ground equipment at either the maximum single application rate (0.5 lbs ai/A) or the typical application rate (0.3 lbs ai/A) result in acute risk quotients for freshwater invertebrates that exceed the restricted use LOC (0.1).

Bromoxynil octanoate, when applied to cotton using either aerial or ground equipment at the maximum application rate of 0.5 lbs ai/A (applied three times), results in acute risk quotients for freshwater invertebrates that exceed the high acute risk LOC (0.5) by a small margin.

All use sites when treated using either ground or aerial equipment, exceed the endangered species LOC (0.05). Therefore, bromoxynil octanoate use may effect endangered invertebrate species.

Chronic

The table below shows the chronic EEC's, from GENEEC, and chronic risk quotients for freshwater invertebrates.

Table 48: Chronic risk quotients for freshwater invertebrates (Species MATC = 3.7 ppb for the *Daphnia magna*)

Crop	Application Method	Application Rate in lbs a.i./A (number of apps.)	21-day EEC (ppb)	Chronic RQ
Corn, Small Grains	Broadcast - ground and aerial	0.5 (1) maximum rate	0.4	0.12
Corn	Broadcast- ground and aerial	0.28 (1) typical rate	0.3	0.07
Small Grains	Broadcast - ground and aerial	0.31 (1) typical rate	0.3	0.07
Cotton	Broadcast- ground	0.5 (3) maximum rate - 10 day application interval	0.9	0.3
Cotton	Broadcast - ground	0.4 (2) typical rate - 10 day application interval	0.7	0.15
Cotton	Aerial	0.5 (3) maximum rate - 10 day application interval	1.0	0.3
Cotton	Aerial	0.4 (2) typical rate - 10 day application interval	0.9	0.3

Based on the aquatic invertebrate MATC from the *Daphnia magna* life-cycle study (3.7 ppb) and 21-day average GENEEC EECs, the use of bromoxynil octanoate represents minimal chronic risk to aquatic invertebrates. Also, based on the GENEEC simulation, concentrations of bromoxynil octanoate are below the MATC by day 4.

(c) Estuarine and Marine Animals

Acute

The table below shows the EEC's, from GENEEC, and acute risk quotients for estuarine/marine organisms.

Table 49: Acute risk quotients for estuarine/marine organisms (Species EC_{50}= 65 ppb for the Mysid)

Crop	Application Method	Application Rate in lbs a.i./A (number of apps.)	Peak EEC (ppb)	Acute RQ
Corn, Small Grains	Broadcast - ground and aerial	0.5 (1) maximum rate	4.5	0.07
Corn	Broadcast- ground and aerial	0.28 (1) typical rate	2.6	0.04
Small Grains	Broadcast - ground and aerial	0.31 (1) typical rate	3.0	0.04
Cotton	Broadcast- ground	0.5 (3) maximum rate - 10 day application interval	9.4	0.15
Cotton	Broadcast - ground	0.4 (2) typical rate - 10 day application interval	8.0	0.12
Cotton	Aerial	0.5 (3) maximum rate - 10 day application interval	10.0	0.15
Cotton	Aerial	0.4 (2) typical rate - 10 day application interval	8.4	0.13

Risk quotients shown are only for the mysid shrimp, which had the lowest EC_{50} of the three estuarine species tested. Risk quotients using the acute toxicity for oysters and fish would not have exceeded any LOCs. Minimal acute risk to oysters and estuarine fish is expected from all bromoxynil octanoate uses.

Bromoxynil octanoate, when applied to cotton using either aerial or ground equipment at both the maximum application rate of 0.5 lbs ai/A (applied three times) or the typical application rate of 0.4 lbs ai/A (applied twice), results in acute risk quotients for estuarine shrimp that exceed the endangered species LOC of 0.05 by a small margin, and slightly exceed the LOC of 0.1 for risk that may be mitigated through restricted use. Therefore, endangered species of estuarine shrimp, may be effected from these uses of bromoxynil octanoate.

Chronic

No chronic data with estuarine species were submitted. Because the freshwater species for both invertebrates and fish are more sensitive than the estuarine species in the acute studies, it is assumed that the conclusion of minimal chronic risk for freshwater species is applicable to estuarine species. Testing on estuarine fish and invertebrates is needed in order to confirm this assumption. Therefore, additional testing (GDLN 72-4) on bromoxynil octanoate is required as confirmatory data.

(3) Exposure and Risk to Nontarget Plants

(a) Terrestrial and Semi-aquatic

Separate risk assessments are done for nontarget terrestrial and semi-aquatic plants. Nontarget terrestrial plants inhabit non-aquatic areas which are generally well drained. Nontarget semi-aquatic plants inhabit low-lying areas that are usually wet, although they may be dry during certain times of the year. Semi-aquatic plants are not obligatory aquatic plants in that they do not live in a continuously aquatic environment. Both the terrestrial and semi-aquatic plants are exposed to pesticides from runoff and drift. They differ, however, in that terrestrial plants are assumed to be exposed via sheet runoff, whereas semi-aquatic plants are assumed to be exposed via channelized runoff. Calculating runoff exposure is done using a simple model which assumes that a certain percent of that which is applied is transported with runoff. The percent is based on solubility. Since the solubility of bromoxynil is 0.08 ppm, it is assumed that no more than 1% of the applied bromoxynil octanoate would run off. Drift from aerial applications is assumed to be 5%, while drift from ground applications would not be expected to exceed 1% of the applied.

Nonendangered Terrestrial and Semi-aquatic Plants

Risk quotients for terrestrial and semi-aquatic plants are derived by dividing an exposure estimate, in lb ai/A, by an EC_{25}, also expressed in lb ai/A. The total loading rate (runoff plus spray drift) is used with the EC_{25} of the most sensitive species in the seedling emergence study to determine the risk quotient for exposure to emerging seedlings. The loading from spray drift alone is used with the EC_{25} value of the most sensitive species in the vegetative vigor study to determine the risk to adult plants from foliar exposure. The following table outlines the acute risk quotients for terrestrial and semi-aquatic plants using results from toxicity testing with bromoxynil octanoate.

Table 50: Exposure and Risk Quotients for Terrestrial and Semi-aquatic Plants

Application method & rate	Plant type	Exposure scenario	Exposure (lb ai/A)	EC_{25} (lb ai/A)	Risk Quotient
Ground, 0.5 lbs ai/A (corn, cotton*, small grains)	Terrestrial	Sheet runoff + spray drift (1%)	0.015	0.12 (seedling emergence)	0.12
	Semi-aquatic	Channelized runoff + spray drift (1 %)	0.09	0.12 (seedling emergence)	0.7
	Terrestrial & semi-aquatic	Spray drift (1%)	0.007	0.017 (veg. vigor)	0.4
Aerial, 0.5 lbs ai/A (corn, cotton*, small grains)	Terrestrial	Sheet runoff + spray drift (5%)	0.04	0.12 (seedling emergence)	0.4
	Semi-aquatic	Channelized runoff + spray drift (5 %)	0.11	0.12 (seedling emergence)	0.9
	Terrestrial & semi-aquatic	Spray drift (5%)	0.04	0.017 (veg. vigor)	2.0

*Cotton use involves multiple applications, however, the model used to estimate exposure does not handle multiple applications well. It is expected that the risk numbers could be higher with multiple applications at 0.5 lbs ai/A.

The LOC (=1) for risk to terrestrial and semi-aquatic plant species has not been exceeded for the highest application rate for either ground or aerial application, with the exception of the spray drift aerial application (RQ = 2.0) which exceeds the LOC by a small margin. This indicates that risk to the vegetative vigor of nontarget terrestrial and semi-aquatic plants may result from exposure to bromoxynil octanoate through drift.

The Agency assumes that risk from bromoxynil octanoate at typical use rates is not greater than the risk from use at the highest application rates, therefore, RQs were not calculated for these rates.

Endangered Terrestrial and Semi-aquatic Plants

Risk quotients for endangered terrestrial and semi-aquatic plants are derived by dividing an exposure estimate, in lb ai/A, by an NOEC, also expressed in lb ai/A. The lowest NOEC for terrestrial plants is 0.015 lb ai/A (MRID 43633701). The risk quotients for endangered plants based on this NOEC compared to the range of exposures predicted would be from 0.3 to 5. This indicates that risk to threatened and endangered terrestrial and semi-aquatic plants may result from exposure to bromoxynil octanoate through runoff and drift.

(b) Aquatic

The same aquatic exposure values used to estimate risk to fish and invertebrates will be used to estimate risk to aquatic plants.

Nonendangered and Endangered Aquatic Vascular Plants

Risk quotients for nonendangered plants are calculated by dividing the GEEC by the aquatic plant EC_{50} values. Risk quotients for endangered plants are calculated by dividing the GEEC by the NOEC.

Data requirements for the aquatic macrophyte (*Lemna gibba*) for bromoxynil octanoate have not been satisfied, however, there are data for bromoxynil heptanoate. Therefore, the risk quotients for aquatic vascular plants used the EC_{50} of 219 ppb (μg/L) (NOEC 77) for duckweed (*Lemna gibba*) based on testing with bromoxynil heptanoate. A study using bromoxynil octanoate is required for confirmatory purposes.

A risk quotient for nonvascular aquatic plants is based on the most sensitive algal or diatom species tested. For bromoxynil octanoate, the most sensitive nonvascular plant tested was the freshwater diatom *Navicula pelliculosa* with an EC_{50} of 51 ppb (μg/L) (NOEC 9.3).

The following table outlines the risk quotients for aquatic vascular plants using results from toxicity testing with bromoxynil heptanoate.

Table 51: Risk quotients for aquatic vascular plants using data from bromoxynil heptanoate (Species EC_{50} = 219 ppb; NOEC = 77 ppb)

Crop	Application Method	Application Rate in lbs a.i./A (number of apps.)	Peak EEC (ppb)	Acute RQ	End. sp RQ
Corn, Small Grains	Broadcast - ground and aerial	0.5 (1) maximum rate	4.5	0.015	0.06
Corn	Broadcast- ground and aerial	0.28 (1) typical rate	2.6	0.01	0.03
Small Grains	Broadcast - ground and aerial	0.31 (1) typical rate	3.0	0.01	0.04
Cotton	Broadcast- ground	0.5 (**3**) maximum rate - 10 day application interval	9.4	0.04	0.12
Cotton	Broadcast - ground	0.4 (2) typical rate - 10 day application interval	8.0	0.04	0.10
Cotton	Aerial	0.5 (**3**) maximum rate - 10 day application interval	10.0	0.04	0.13
Cotton	Aerial	0.4 (2) typical rate - 10 day application interval	8.4	0.04	0.1

Typical and maximum applications of bromoxynil heptanoate do not represent a risk to aquatic vascular plants, however, overall risk to aquatic vascular plants cannot be dismissed at this time due to the lack of data. In order to fully assess the risk to aquatic vascular plants from bromoxynil octanoate, testing with *Lemna gibba* is required.

The following table outlines the risk quotients for aquatic nonvascular plants using results from toxicity testing with bromoxynil octanoate:

Table 52: Risk quotients for aquatic nonvascular plants (representing algae and diatoms) (Species EC_{50} = 51 ppb; NOEC = 9.3 ppb)

Crop	Application Method	Application Rate in lbs a.i./A (number of apps.)	Peak EEC (ppb)	Acute RQ	End. sp RQ
Corn, Small Grains	Broadcast - ground and aerial	0.5 (1) maximum rate	4.5	0.09	0.4
Corn	Broadcast- ground and aerial	0.28 (1) typical rate	2.6	0.04	0.3
Small Grains	Broadcast - ground and aerial	0.31 (1) typical rate	3.0	0.06	0.3
Cotton	Broadcast- ground	0.5 (3) maximum rate -10 day application interval	9.4	0.2	1.0
Cotton	Broadcast - ground	0.4 (2) typical rate - 10 day application interval	8.0	0.16	0.9
Cotton	Aerial	0.5 (3) maximum rate - 10 day application interval	10.0	0.2	1.0
Cotton	Aerial	0.4 (2) typical rate - 10 day application interval	8.4	0.16	0.9

Use of typical and maximum applications to many of the large acreage crops for which bromoxynil octanoate is registered do not represent a risk to nonendangered aquatic nonvascular plants. The risk quotients for endangered aquatic plants range from 0.03 to 1.0. The LOC (1) for endangered plants has been met for the maximum application rate to cotton. Therefore, use of the maximum application rate on cotton may represent a risk to endangered aquatic nonvascular plants.

(4) Endangered Species

The use of bromoxynil octanoate may adversely effect endangered species of birds and mammals, both acutely and chronically; fish and invertebrates (both freshwater and estuarine/marine species) acutely; and terrestrial, semi-aquatic, and aquatic nonvascular plants.

When the Endangered Species Protection Program becomes final, limitations in the use of bromoxynil octanoate may be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. EPA anticipates that a consultation with the Fish and Wildlife Service may be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

b. Environmental Risk Characterization

(1) Background Information

The Agency concentrated on data for bromoxynil octanoate because it was found to be chemically and physically similar to bromoxynil heptanoate (one carbon difference in the ester chain) and both esters hydrolyze, photolyze and can microbially metabolize to bromoxynil (phenol) which further degrades to CO_2. The heptanoate ester was registered based on bridging data for bromoxynil octanoate. Also, bromoxynil octanoate and bromoxynil (phenol) were determined to be toxicologically equivalent on a molar basis. In the risk assessment, toxicity data for bromoxynil octanoate, with the exception of aquatic vascular plants, was used to estimate risk. This is consistent with the fate information in that fate parameters were derived from testing with the octanoate. In most cases, the octanoate was more toxic to test species than bromoxynil heptanoate.

(2) Environmental Fate and Transport Assessment

Based on available information from environmental fate studies, the fate and transport of bromoxynil octanoate under laboratory and field conditions is adequately known. Results from the laboratory studies done on the TGAI (e.g., octanoate or heptanoate) are consistent with the field study results where the end use product (mixtures of the different technicals) is used.

Bromoxynil octanoate is mobile and is non-persistent. It dissipates in the environment by hydrolysis, photolysis, and microbially-mediated metabolism. Residues are more likely to be found in surface runoff waters, but it is not expected to persist in surface waters. Bromoxynil octanoate accumulates in bluegill sunfish, however, depuration occurs by Day 14. Bromoxynil octanoate was not persistent in the field.

Based on environmental fate information the potential for ground water contamination from bromoxynil octanoate is low. Limited monitoring information for ground water is available. Surface water monitoring is described in section 2(c)2.

(3) Risk to Nontarget Animals

Endocrine Effects: Bromoxynil octanoate has been shown to impair reproduction in birds, fish, and aquatic invertebrates. The nature of the impairment observed, lesions of old yolk peritonitis, regressing ovaries, and reduced number of viable embryos in birds, and decreased growth and embryo hatching

success in fish, suggests an endocrine disruption etiology. Although the available information indicates that the risk of exposures sufficient enough to elicit endocrine disruption is minimal, bromoxynil octanoate should still be considered a potential endocrine disputer and candidate for future screening and testing of this mode of action.

Birds: The *acute* risk to birds from bromoxynil octanoate is expected to be low. The avian LOC for endangered species (0.1) has been slightly exceeded for all modeled use rates on short grasses; using both single and multiple applications; and on broadleaf plants and insects. Therefore, a may effect for endangered birds has been identified. The risk quotients at the maximum use rate for cotton, with three applications, exceed the restricted use LOC (0.2) by a small margin on short grasses.

The overall *chronic* risk to birds from bromoxynil octanoate is expected to be low. A *chronic* "may affect" for endangered birds has been identified for the two highest use rates on short grasses and on broadleaf plants and insects. The RQs, based on day 0 concentrations, which rapidly decrease due to degradation (hydrolysis/photolysis) and metabolism, ranged from 0.12 to 3. EECs are predicted to exceed the mallard NOEL (102 ppm) for up to 7 days on short grasses.

Currently, no chronic avian data for bromoxynil phenol are available. The phenol is substantially less acutely toxic to birds than the octanoate. Likewise, it can be presumed that the phenol would be less toxic on a chronic basis than the octanoate. The octanoate readily hydrolyzes to the phenol, which is the compound birds would be exposed to in the long term. Therefore, it is likely that chronic risk to birds from bromoxynil would be low.

Mammals: The *acute* risk to mammals, including threatened and endangered species, from exposure to bromoxynil octanoate is expected to be low. LOCs for acute risk and restricted use were marginally exceeded at the higher application rates for the meadow vole and the least shrew. The LOC for presumption of risk to endangered species was exceeded for the higher application rates for the vole, the field mouse, and the least shrew. In addition, a 2-generation reproductive toxicity study with rats reported no mortality at levels greater than 250 ppm (NOEL for acute and subacute effects). The maximum estimated concentration on mammalian food items is 180 ppm. Because the maximum EEC is less than the NOEL, where no effects, either sublethal or lethal occurred, it is unlikely that mammals (including endangered species) would be exposed to enough bromoxynil octanaote to cause adverse acute effects.

The *chronic* risk to mammals, including threatened and endangered species, would be expected to be high if mammals were exposed to high enough residues of bromoxynil octanoate. Although the

RQs were not excessively high (0.2-5.2), bromoxynil has been shown to be a developmental toxicant in several toxicology studies. The data suggest a high risk of reproductive impairment. If mammals were exposed to bromoxynil at high enough levels, chronic developmental effects may occur. Small mammals do use corn and cotton fields for cover, brood rearing, and foraging. It is also likely that they would be present during time of application as well as before and after. It appears that use of bromoxynil may have adverse impacts to mammals on a chronic basis.

Fish: The overall *acute* risk to freshwater fish from exposure to bromoxynil octanoate is expected to be low. The endangered species LOC has been exceeded based on results from all modeled use sites, therefore, applications of bromoxynil octanoate may affect endangered freshwater fish species. The environmental fate characteristics of bromoxynil octanoate indicate that once it is in the aqueous environment, it hydrolyzes readily to the phenol, which is practically nontoxic, and then further degrades to CO_2. Therefore, endangered species are likely to be acutely affected only during the short time before the octanoate degrades (half-lives of 1-11 days). Likewise, the *acute* risk to estuarine fish is expected to be low.

The *chronic* risk to freshwater fish and estuarine fish from exposure to bromoxynil octanoate is expected to be minimal. No LOCs were exceeded. Again, bromoxynil octanoate is not likely to remain in water long enough to cause chronic adverse effects. However, because the catfish appears to be more sensitive on an acute level, it may be more sensitive on a chronic level. The MATC for the catfish may be lower than that for the fathead minnow, but it is still unlikely that any LOCs would be exceeded based on the low EECs. It was assumed that the chronic assessment for freshwater species is applicable to estuarine species.

In order to further address the risk to aquatic organisms from bromoxynil octanoate application to transgenic cotton, Tier 2 PRZM-EXAMS modeling was performed using environmental fate information for bromoxynil (Section 2.c.(2)). The EECs ranged from 12.3 ppb (peak) to 2.5 ppb (60 day). Although the bromoxynil phenol EECs were higher than the bromoxynil octanoate EECs, bromoxynil phenol is substantially less toxic to aquatic organisms than the octanoate, therefore, the risk is minimal. The overall acute risk to freshwater fish from exposure to bromoxynil due to application of bromoxynil octanoate to transgenic cotton is expected to be low. No LOCs were exceeded.

Invertebrates: The overall *acute* risk to freshwater invertebrates is expected to be medium. All use sites exceed the endangered species LOC, therefore, the use of bromoxynil octanoate may affect endangered invertebrates. The high risk LOC has also been exceeded slightly for the cotton use and the restricted use LOC has been exceeded for cotton, corn, and small grains uses. When a restricted

use LOC has been exceeded, this suggests that risk to the nontarget species may be mitigated through restricted use labeling. This increases the possibilities that the pesticide will be handled properly, and label directions followed, in order to minimize exposure and thus reduce risk. Although bromoxynil octanoate degrades rapidly in the aqueous environment, it is likely to remain for a duration long enough to cause acute effects.

The overall *acute* risk to estuarine organisms is expected to be low. The endangered species LOC (0.05) for estuarine shrimp has been exceeded by a small margin for bromoxynil octanoate when applied to cotton (both typical and maximum application rates), therefore, applications of bromoxynil octanoate may affect endangered estuarine shrimp species. However, there are no endangered estuarine shrimp species at this time. The endangered species are likely to be acutely affected during the short time before the octanoate degrades (half-lives of 1-11 days).

The *chronic* risk to freshwater and estuarine invertebrates is expected to be minimal. No LOCs were exceeded. Bromoxynil octanoate is unlikely to remain in water long enough to cause chronic effects. It was assumed that the chronic assessment for freshwater species is applicable to estuarine species. Chronic testing with estuarine fish and invertebrates are needed in order to confirm this assumption (GLN 72-4).

The overall acute risk to freshwater invertebrates from exposure to bromoxynil due to application of bromoxynil octanoate to transgenic cotton is expected to be low. No LOCs were exceeded.

(4) Risk to Nontarget Plants

Terrestrial and Semi-aquatic: The overall risk to both endangered and non-endangered terrestrial and semi-aquatic plants is expected to be medium. The LOCs were exceeded for spray drift from the aerial application of bromoxynil octanoate at the maximum label rate. This indicates that risk to the vegetative vigor of nontarget terrestrial and semi-aquatic plants may result from exposure to bromoxynil octanoate through drift. Although the LOCs were only exceeded by a small margin, the risk to these plants is likely underestimated because the model does not take into account multiple applications. An incident reported from the State of Oregon also supports the assumption of risk to nontarget terrestrial and semi-aquatic plants (I# 001664). In 1994, the Oregon Department of Agriculture received a report of an aerial application of several pesticides inconsistent with their labeling. As a result of this, pea fields, approximately ½ mile from the wheat fields being treated, exhibited adverse symptoms consistent with those attributed to the herbicides used on the wheat. Analyses of samples taken from the pea field determined the presence of bromoxynil octanoate residues consistent with that applied to the wheat fields.

Aquatic: Risk to aquatic vascular plants (endangered and non-endangered) from the use of bromoxynil octanoate is uncertain at this time. An estimate of risk (based on data from bromoxynil heptanoate) indicated that aquatic vascular plants are not likely to be affected by bromoxynil octanoate application. However, in order to confirm risk to aquatic vascular plants, bromoxynil octanoate testing with *Lemna gibba* is required.

Risk to aquatic nonvascular plants (endangered and nonendangered) is expected to be minimal. The LOC for endangered species was met, but not exceeded for the maximum application rate to cotton using EEC's derived from GENEEC. Using Tier II EECs and taking into account all of the available toxicity information, overall risk to aquatic plants due to bromoxynil from application of bromoxynil octanoate to transgenic cotton is expected to be low. Since this is the highest exposure scenario, overall risks are expected to be low.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing bromoxynil as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing bromoxynil. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of the reregistration eligibility of bromoxynil, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of bromoxynil and to determine that bromoxynil can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing bromoxynil as an active ingredient are eligible for reregistration provided the registrant follows all requirements as set forth in this document. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, and the data identified in Appendix B. Although the Agency has

found that all uses of bromoxynil are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing bromoxynil, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient bromoxynil, the Agency has sufficient information on the health effects of bromoxynil and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that bromoxynil products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks to humans or the environment. Therefore, the Agency concludes that products containing bromoxynil for all uses are eligible for reregistration, provided the registrant follows all requirements as set forth in this document.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of bromoxynil are eligible for reregistration, provided the registrant follows all requirements as set forth in this document.

B. Regulatory Position

The following is a summary of the regulatory positions and rationales for bromoxynil. Where labeling revisions are imposed, specific language is set forth in Section V. of this document.

1. Tolerance Reassessment

Based on the tolerances published in the FR Notice dated 6/18/97 and the FR Notice dated 5/13/98, and on additional data, proposed label amendments, and clarification of the Agency's policy on 40 CFR §180.6(a)(3), a revised tolerance reassessment summary was required and is provided below.

Separate tolerance expressions listed under 40 CFR §180.324(a), (b), and (c) were redundant, and, therefore, the tolerance expression is revised to delete tolerances listed under §180.324(b) and (c), and to place reassessed and new tolerances under §180.324(a). The 6/18/97 FR Notice provided a revised §180.324(a), with the previously recommended tolerances under §180.324(a)(1), and tolerances for residues in cotton and livestock commodities under §180.324(a)(2). In addition, it is noted that

§180.324(b), (c), and (d) are reserved for Section 18 emergency exemptions, tolerances with regional registrations, and indirect or inadvertent residues, respectively. The revised tolerance reassessment table reflects the changes associated with the establishment of tolerances for residues in cotton commodities. Note that tolerances for residues in livestock commodities have been moved from 180.324(a)(1) to 180.324(a)(2) based on a determination that secondary residues of the metabolite DBHA transfer to livestock.

The tolerance expression for §180.324(a)(1)is as follows:

> "Tolerances are established for residues of the herbicide bromoxynil (3,5-dibromo-4-hydroxybenzonitrile) resulting from application of its octanoic and/or heptanoic acid ester in or on the following commodities:"

The tolerance expression for §180.324(a)(2) is as follows:

> "Tolerances are established for residues of the herbicide bromoxynil (3,5-dibromo-4-hydroxybenzonitrile) and its metabolite 3,5-dibromo-4-hydroxybenzoic acid resulting from application of its octanoic and/or heptanoic acid ester in or on the following commodities:"

Table 53: Revised Tolerance Reassessment Summary

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR §180.324 (a)(1):			
Alfalfa, seedling	0.1	Revoke	Tolerances should be proposed for alfalfa forage and hay (see below).
Barley, forage, green	0.1	Revoke	Barley forage is no longer a regulated feed item.
Barley, grain	0.1	0.05	Based upon available residue data, tolerances for residues in all cereal grains should be lowered to 0.05 ppm.
Barley, straw	0.1	4.0	The proposed tolerance is supported by the available data.
Corn, fodder, (dry)	0.1	Revoke	Tolerances are already established for residues in field corn commodities and separate tolerances should be established for residues in pop corn commodities.
Corn, forage, (green)	0.1		
Corn, grain	0.1		
Corn, fodder, field (dry)	0.1	0.2	The proposed tolerance is supported by available data; *Corn, field, stover*.
Corn, forage, field (green)	0.1	0.3	Based upon available data, the tolerance should be increased; *Corn, field, forage*.
Corn, grain, field	0.1	0.05	See comment under barley grain; *Corn, field, grain.*
Flaxseed	0.1	0.1	*Flax, seed.*
Flax straw	0.1	Revoke	Flax straw is no longer a regulated feed item.
Garlic	0.1	0.1	

Table 53: Revised Tolerance Reassessment Summary

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Grass, canary, annual, seed	0.1	Revoke	Concomitant with establishing tolerances in grass commodities, tolerances for residues in canary grass seed and straw should be revoked.
Grass, canary, annual, straw	0.1		
Mint hay	0.1	0.1	*Peppermint, tops* and *Spearmint, tops*.
Oats, forage, green	0.1	0.3	Based on residue data translated from barley forage, the tolerance should be increased; *Oats, forage*.
Oats, grain	0.1	0.05	See comment under barley grain.
Oats, straw	0.1	4.0	Based on residue data translated from barley straw, the tolerance should be increased.
Onions (dry bulb)	0.1	0.1	*Onion, bulb*
Rye, forage, green	0.1	1.0	Based on residue data translated from wheat forage, the tolerance should be increased; *Rye, forage*.
Rye, grain	0.1	0.05	See comment under barley grain.
Rye, straw	0.1	2.0	See comment under wheat, straw.
Sorghum, fodder	0.1	0.2	Based on available residue data, the tolerance should be increased.
Sorghum, forage	0.1	0.5	
Sorghum, grain	0.1	0.05	See comment under barley grain.
Wheat, forage, green	0.1	1.0	Based on available data, the tolerance should be increased; *Wheat, forage*.
Wheat, grain	0.1	0.05	See comment under barley grain.
Wheat, straw	0.1	2.0	Based on available data, the tolerance should be increased.
Tolerances to be Listed under 40 CFR §180.324(a)(2):			
Cotton gin by-products	50	7.0	Originally established as stated in the FR Notice dated 6/18/97
Cotton hulls	21	5.0	
Cotton, undelinted seed	7	1.5	
Cattle, fat	0.1	1.0	Based upon the available feeding study data, tolerances should be increased.
Cattle, mbyp	0.1	3.5	
Cattle, meat	0.1	0.5	
Milk	None	0.1	The registrant should propose the tolerance for residues in milk, based on data from the ruminant feeding study.
Hogs, fat	0.1	1.0	Based upon the available feeding study data, tolerances should be increased [tolerances translated from cattle].
Hogs, mbyp	0.1	3.5	
Hogs, meat	0.1	0.5	
Horses, fat	0.1	1.0	Based upon the available feeding study data, tolerances should be increased [tolerances translated from cattle].
Horses, mbyp	0.1	3.5	
Horses, meat	0.1	0.5	
Poultry, meat	None	0.05	Residues in poultry can no longer be classified under Category 3 of 40 CFR §180.6(a).
Poultry, fat	None	0.05	
Poultry, eggs	None	0.05	

Table 53: Revised Tolerance Reassessment Summary

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Poultry, mbyp	None	0.3	
Goats, fat	0.1	1.0	Based upon the available feeding study data, tolerances should be increased.
Goats, mbyp	0.1	3.5	
Goats, meat	0.1	0.5	
Sheep, fat	0.1	1.0	Based upon the available feeding study data, tolerances should be increased [tolerances translated from cattle].
Sheep, mbyp	0.1	3.5	
Sheep, meat	0.1	0.5	
New Tolerances Required under 40 CFR §180.324(a)(1):			
Alfalfa, hay	None	0.5	The registrant should propose the tolerance, based on available data.
Alfalfa, forage	None	0.1	The registrant should propose the tolerance, based on available data.
Aspirated grain fractions	None	0.3	The registrant should propose the tolerance, based on available data.
Barley, hay	None	9.0	The registrant should propose the tolerance, based on available data.
Corn, pop, fodder	None	0.2	The registrant should propose the tolerance, based on available data; *Corn, pop, stover*.
Corn, pop, grain	None	0.05	See comment under barley grain; *Corn, pop, grain*
Grass, forage	None	3.0	A crop group tolerance should be proposed for residues in forage and hay of grasses. Note that grass forages/hay have not been included in ruminant diets, since bromoxynil is only used on grass grown for seed and on grass grown under the CRP. Changes in the use on grass may require revision of livestock tolerances.
Grass, hay	None	3.0	
Oats, hay	None	9.0	The registrant should propose the tolerance, based on available barley hay data.
Wheat, hay	None	4.0	The registrant should propose the tolerance, based on available wheat hay data.
§180.324(b) Section 18 emergency exemptions [Reserved]			
§180.324(c) Tolerances with regional registrations [Reserved]			
§180.324(d) Indirect or inadvertent [Reserved]			

CODEX HARMONIZATION

Since there are no established or proposed Codex MRLs for bromoxynil residues, no compatibility questions exist with respect to U.S. tolerances and Codex.

2. Summary of Risk Management Decisions

a. Human Health

(1) Dietary

FQPA

EPA has determined that the established tolerances for bromoxynil, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) requiring a reasonable certainty of no harm for the general population. In reaching this determination, EPA has considered the available information on the aggregate exposures (both acute and chronic) from food and drinking water. There are no residential exposures from bromoxynil. For cumulative effects, in the case of bromoxynil, EPA has not yet conducted a detailed review of common mechanism to determine whether it is appropriate, or how to include this chemical in a cumulative risk assessment. After EPA develops a methodology to incorporate common mechanism of toxicity evaluations in risk assessments, the Agency will develop a process (either as part of the periodic review of pesticides or otherwise) to reexamine these tolerance decisions. For the purpose of the tolerance reassessment in this RED, EPA has assumed that bromoxynil does not have a common mechanism of toxicity with other non-bromoxynil substances.

Children

EPA has determined that the established tolerances for bromoxynil, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) for infants and children. The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of bromoxynil residues in this population subgroup.

Based on the current data requirements, bromoxynil has a complete database for developmental and reproductive toxicity. Studies cited earlier in this document indicate a well-established developmental endpoint (supernumerary ribs) which occurs at dose levels lower than those that show evidence of maternal toxicity. The Agency has concluded that the FQPA safety factor is necessary to protect the developing fetus due to evidence of increased susceptability for that sensitive subpopulation. EPA based its decision upon concerns emanating from the toxicological profile, including evidence of increased susceptibility of fetuses to bromoxynil exposure, although it is recognized that there are

extensive and reliable data available and there are no outstanding uncertainties regarding the effects on developing animals following pre- and/or postnatal exposure to bromoxynil. Therefore the Agency retained the FQPA safety factor only for the population consisting of females 13+ to protect the developing fetus from effects resulting from *in utero* exposure.

In deciding to continue to make reregistration determinations during the early stages of FQPA implementations, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early, case-by case decisions, EPA does not intend to set broad precedents for the application of FQPA to its regulatory determinations. Rather, these early decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will consider itself free to pursue whatever action may be appropriate, including but not limited to, reconsiderations of any portion of this RED.

The dietary findings are summarized below.

Acute Dietary

The acute dietary risks (calculated as MOEs) from food sources (including cotton) for the general population and subgroups are all greater than 10,000, indicating that there is no acute risk concern resulting from exposure to bromoxynil. There appears to be no acute risk to the general population or any subgroup from drinking water. The acute MOEs calculated for drinking water are >10,000. The aggregate acute risks from food, including cotton, and water for the general population and all subgroups are all greater than 10,000, indicating there is no aggregate acute risk concern.

Chronic Dietary (including cancer)

There is no chronic risk from food sources or drinking water, both of which have a risk of < 1% of the RfD. The aggregate chronic risks from food and water is also <1% of the RfD for the general population and all subgroups. The Agency considers percentages approaching 100% to be of concern. Therefore, there is no chronic risk concern.

The cancer risk from food sources is above 1.5×10^{-6}. This risk estimate is based on anticipated residues and percent crop treated data which represent the most refined estimate the Agency can currently conduct. One of the assumptions made in the risk assessment is that 10% (1.3 million acres) of the cotton crop is treated with bromoxynil. Treatment of >10% cotton acreage is not permitted

under the current registration. Changes in the percent crop treated will necessarily change the risk estimate. There appears to be no cancer risk from drinking water alone with risk calculated to be 0.2 x 10^{-6} . The aggregate dietary cancer risk from food and water consumption was calculated to be 1.7 x 10^{-6}. This risk represents a worst case scenario.

The Agency has determined the aggregate cancer risk from bromoxynil meets the reasonable certainty of no harm standard. EPA believes that, given the weight-of-the-evidence, the bromoxynil risk is "negligible". The Agency does not apply the negligible risk standard as a bright line test because of the lack of precision in quantitative cancer risk assessment. There are a significant number of uncertainties in both the toxicological data used to derive the cancer potency of a substance and in the data used to measure and calculate exposure.

Endocrine Disrupter Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

b. Environmental

No risk mitigation is required at this time as the result of ecological effects concerns. While there were some small exceedances of levels of concern (LOCs), generally the risks from the use of bromoxynil are relatively low. These risks are summarized below. Outstanding data requirements include: 123-2 with *Lemna gibba*; and 172-4 (a & b) for chronic estuarine toxicity testing.

(1) Avian

Acute

The acute risk to birds is considered to be low. A may effect for endangered avian species has been identified. No risk quotient exceeded 0.3.

Chronic

The chronic risk to birds is considered to be low. A chronic may effect for endangered birds has been identified for the two highest use rates for cotton on short grasses. No risk qotient exceeded 3.0. Bromoxynil phenol is substantially less acutely toxic to birds than the octanoate. It can be presumed that it would also be less toxic on a chronic basis. Since the octanoate readily degrades to the phenol, the compound to which birds would be exposed to on a chronic basis is the phenol.

(2) Mammals

Acute

The acute risk to mammals, including threatened and endangered species, from exposure to bromoxynil octanoate is expected to be low. LOCs for high acute risk, restricted use and endangered species were slightly exceeded at the higher application rates for the meadow vole and the least shrew. No risk quotient exceeded 0.24.

Chronic

The chronic risk to mammals, including threatened and endangered species, from exposure to bromoxynil octanoate would be expected to be high if mammals were exposed to high enough residues. Although the risk quotients (RQs) were not excessively high (0.2 - 5.2), bromoxynil octanoate has been shown to be a developmental toxicant in several studies. If mammals were exposed to bromoxynil at high enough levels, chronic developmental effects may occur. However, such levels are believed to be unlikely to occur.

(3) Insects

Bromoxynil octanoate is practically non-toxic to bees; therefore minimal risk is presumed.

(4) Freshwater Fish

The acute risk to freshwater fish is expected to be low. Using EECs derived from GENEEC, no risk quotient exceeds 0.4. The endangered species LOC has been slightly exceeded based on results from all modeled use sites, therefore, applications of bromoxynil octanoate may affect endangered freshwater fish species. However, the environmental fate characteristics of the chemical indicate that once it is in the aqueous environment, it metabolizes readily to the phenol, which is practically nontoxic to freshwater fish, and then further degrades to CO_2. Therefore, endangered species are likely to be

exposed only a short time before the octanoate degrades (half life of 1-14 days). The overall chronic risk to freshwater fish is anticipated to be minimal.

(5) Estuarine and Marine Organisms

Acute risk quotients derived from GENEEC using the lowest EC_{50} value of three estuarine species tested (mysid shrimp), ranged from 0.04 - 0.15. Acute toxicity of bromoxynil to oysters and estuarine fish is less than that for the shrimp, therefore, minimal acute risk to oysters and estuarine fish is expected from all bromoxynil octanoate uses.

No chronic data with estuarine species were submitted. Because the freshwater species for both invertebrates and fish are more sensitive than the estuarine species in the acute studies, it is assumed that the conclusion of minimal chronic risk for freshwater species is applicable to the estuarine species. Additional data on bromoxynil octanoate are required as confirmatory data.

(6) Aquatic invertebrates (Freshwater and Estuarine/Marine)

The overall acute risk to freshwater invertebrates is expected to be low. Risk quotients, using EECs derived from GENEEC range from 0.3 to 0.9. For the cotton scenario, which represents the worst case, EECs from the Tier II model (PRZM-EXAMS) were used. In this case no LOCs were exceeded. The acute risk to estuarine organisms is expected to be low. The acute endangered species LOC for estuarine shrimp has been exceeded by a small margin for the cotton use. However, there are currently no endangered estuarine shrimp species. Based on the *Daphnia magna* life-cycle study and the EECs calculated from GENEEC, the chronic risk to aquatic invertebrates is expected to be minimal. Risk quotients ranged from 0.07 - 0.15. The environmental fate characteristics of bromoxynil indicate that once it is in the aqueous environment, it metabolizes readily to the phenol, which is practically nontoxic, and then further degrades to CO_2. Therefore, endangered species are likely to be exposed only a short time before the octanoate degrades (half life of 1-14 days).

(7) Nontarget Plants (Terrestrial, Semi-Aquatic, and Aquatic)

The overall risk to both endangered and non-endangered terrestrial and semi-aquatic plants is expected to be medium. However, compared to other herbicides, it is relatively low. The only LOC exceeded is for spray drift from the aerial application of bromoxynil octanoate at the maximum label rate. This LOC indicates that risk to the vegetative vigor of nontarget terrestrial and semi-aquatic plants may result from exposure to bromoxynil octanoate through drift. The LOCs were exceeded by only a small margin (RQ=2.0). However, this risk may be underestimated for the cotton use, which allows multiple applications, because the exposure model used does not account for multiple applications. Label language addressing spray drift concerns is required.

Risk to aquatic vascular plants (endangered and non-endangered) from the use of bromoxynil octanoate appears to be low. An estimate of risk (based on data from bromoxynil heptanoate) indicated that aquatic vascular plants are not likely to be affected by bromoxynil octanoate application. However, in order to confirm this assessment, bromoxynil octanoate testing with *Lemna gibba* is required.

Risk to aquatic nonvascular plants (endangered and nonendangered) is expected to be minimal. The LOC for endangered species was met, but not exceeded for the maximum application rate to cotton. Taking into account all of the available toxicity information, overall risk to aquatic plants due to bromoxynil from application of bromoxynil octanoate to transgenic cotton is expected to be low.

(8) Endangered Species

See applicable sections under each category above.

(9) Surface Water

Information from environmental fate studies indicates that bromoxynil octanoate should not persist in surface waters. Risks to aquatic organisms are expected to be low.

(10) Ground Water

The potential for ground water contamination from bromoxynil is low. Bromoxynil octanoate readily degrades to bromoxynil phenol via hydrolysis. Although bromoxynil phenol has the potential to leach to ground water under certain conditions, its rapid aerobic and anaerobic degradation reduces the likelihood of ground water contamination. Based on the results from the laboratory and terrestrial field dissipation studies, bromoxynil octanoate does not have the mobility or persistence characteristics of pesticides that are normally found in ground water.

c. Restricted Use Classification

None of the products containing bromoxynil as the active ingredient are classified as restricted use. No action to classify any use as restricted is required.

d. Reference Dose Exceedance

Only < 1% of the RfD is occupied by the current uses of bromoxynil. There is no exceedence concern.

e. Endangered Species Statement

Levels of concern for endangered avian, terrestrial and aquatic plant and mammal species were exceeded for bromoxynil, as discussed above in the science section.

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures where necessary. The program may require use restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register and have available voluntary county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

f. Labeling Rationale

In order to remain in compliance with FIFRA, it is the Agency's position that the labeling of all registered pesticide products containing bromoxynil must comply with the Agency's current pesticide labeling requirements. The Agency has determined that the current manufacturing and end-use label precautions are still appropriate and required for product reregistration. In addition, it is the Agency's position that the label statements/precautions listed in Section V of this RED must be included on all affected products in order to remain in compliance with FIFRA.

g. Spray Drift Advisory

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation to develop the best spray drift management practices. The Agency is now requiring interim measures that must be placed on product labels/labeling as specified in Section V. Once the Agency completes its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, the Agency may impose further refinements in spray drift management practices to further reduce off-target drift and risks associated with this drift.

h. Occupational and Residential Labeling Rationale/Risk Mitigation

At this time, all products containing bromoxynil are intended primarily for occupational use (i.e. mixed, loaded, and applied by commercial applicators only and generally not available to homeowners). No registered use is allowed at residential sites.

(1) The Worker Protection Standard (WPS)

EPA's Worker Protection Standard for Agricultural Pesticides (WPS) affects all pesticide products whose labeling reasonably permits use in the commercial or research production of agricultural plants on any farm, forest, nursery, or greenhouse. In general, WPS products had to bear WPS-complying labeling when sold or distributed after April 21, 1994. The WPS labeling requirements pertaining to personal protective equipment (PPE), restricted-entry intervals (REI), and notification are interim. These requirements are to be reviewed and revised, as appropriate, during reregistration and other Agency review processes. At this time some of the registered uses of bromoxynil are within the scope of the WPS and some uses are outside the WPS scope.

(2) Determination of Requirements for Handlers

For each end-use product, personal protective equipment and engineering control requirements for pesticide handlers are set during reregistration as follows:

- Based on risks posed to handlers by the active ingredient, EPA may establish active-ingredient specific (a.i. specific) handler requirements for end-use products containing that active ingredient. If such risks are minimal, EPA may choose not to establish a.i. specific handler requirements.

- EPA establishes handler PPE requirements for most end-use products based on each product's acute toxicity characteristics.

- If a.i. specific requirements have been established, they must be compared to the PPE specified for the end-use product. The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product. Engineering controls are considered more stringent than PPE requirements.

3. Occupational-Use Products (WPS Uses and Non-WPS Uses)

EPA is establishing a.i. specific requirements for occupational handlers for bromoxynil. Since potential handler exposure is similar for WPS and nonWPS uses, the a.i. specific handler requirements are the same for WPS and nonWPS occupational uses of bromoxynil end-use products.

EPA has established a short- and intermediate-term dermal NOEL for bromoxynil based on developmental effects and has also classified bromoxynil as a Group C quantifiable carcinogen. The handler dermal risk assessment based on the Pesticide Handler's Exposure Database (PHED) data for mixers/loaders/applicators indicates that short- and intermediate-term dermal risks and cancer risks are acceptable (i.e., greater than 100) if such handlers wear chemical-resistant gloves in addition to baseline attire (long-sleeve shirt, long pants, shoes, and socks) while performing mixing and loading tasks and baseline attire while performing applicator tasks. For all tasks, other than mixing and loading, the risks are acceptable for handlers with baseline attire. The cancer risk for the non-commercial handlers (grower) is 2×10^{-6} or lower for all scenarios with baseline attire, except that mixers and loaders must also wear chemical-resistant gloves. The cancer risk for commercial handlers is 1.9×10^{-5} or lower for all scenarios with baseline attire, except that mixers and loaders must also wear chemical-resistant gloves. The highest cancer risk estimate from these particular scenarios was 1.9×10^{-5} (commercial mixer/loaders for aerial applications and sprinkler irrigation). However, these mixer/loader risk estimates do not account for the potential exposure reduction from the use of "wide-mouth" containers (designed to reduce spillage) for mixer/loaders. At the present time the PHED database does not allow the Agency to quantify this risk mitigation measure, however the use of the "wide-mouth" containers would likely reduce the reported risk further. In addition to provide an additional margin of safety, EPA is requiring mixers and loaders to wear a chemical-resistant apron. Although EPA has no data to specifically assess the exposure reduction to mixers/loaders afforded by a chemical-resistant apron, the Agency is persuaded that the exposure reduction would be significant. Available data indicate that the preponderance of non-hand exposure to mixers/loaders is to the front torso.

EPA has determined that occupational exposures to bromoxynil would be adequately mitigated with the following PPE: mixers/loaders wearing long sleeved shirts, long pants, shoes, and socks plus chemical resistant gloves while using open mixing/loading. All other handlers (i.e., applicators, flaggers, etc.) must wear baseline attire (i.e., long-sleeve shirt, long pants, shoes, and socks). For applicators using fixed- and rotary-wing aircraft to apply bromoxynil, the risks are acceptable (i.e., 310) when enclosed cockpits are assumed. Since the Pesticide Handlers Exposure Database does not contain sufficient data to estimate exposure to applicators using aircraft with open cockpits, only exposure for aerial applicators using engineering controls, (i.e., enclosed cockpits) was estimated. However, the

MOEs are acceptable at baseline attire for applicators using groundboom equipment and for flaggers, and the MOEs are high for applicators using enclosed cockpits, therefore, EPA does not have concerns for handlers who may apply bromoxynil using aircraft with open cockpits. Since risks are acceptable for human flaggers without engineering controls, the existing labeling requirements that "human flaggers are prohibited unless in enclosed vehicles" is not being retained.

Engineering-control requirements would also contribute to exposure reduction for mixers and loaders. Some bromoxynil end-use products are already formulated to provide a type of engineering control exposure-reduction for mixers and loaders. These include products formulated in water-soluble gel packets and those formulated in wide-mouth jugs designed to reduce splashing. These offer additional protection for mixers and loaders.

The Agency is retaining the present labeling restrictions regarding chemigation, including that (1) hand-moved pipe must not be handled in any way until 24 hours after chemigation has been completed and residues have been flushed from the system, and (2) no person may enter the application site during the chemigation, except in an enclosed vehicle.

The Agency is also retaining the present labeling restrictions regarding prohibiting aerial application within 300 feet of residential areas, including homes, schools, playgrounds, shopping areas, and hospitals. Also being retained are the present labeling restrictions regarding application to non-residential turf only. The labeling will specifically prohibit applications to residential, playground, or schoolyard turf.

The Agency is retaining and expanding the present labeling restrictions regarding application with backpack or hand-held application equipment. Presently the label prohibits application to non-residential turf with such equipment. The new label statement will prohibit application to any crop with backpack or hand-held application equipment.

Finally, since the Agency has determined that the heptanoate ester is toxicologically equivalent to the octanoate ester, the handler requirements established here also apply to end-use products containing the heptanoate ester.

4. Post-Application/Entry Restrictions

a. Occupational-Use Products (WPS Uses)

Restricted-entry intervals, early-entry PPE, and "double" notification:

The interim Worker Protection Standard (WPS) restricted-entry intervals (REI's) for agricultural workers are based solely on the acute dermal toxicity and skin and eye irritation potential of the active ingredient. In addition, the WPS retains two types of REI's established by the Agency before the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data, and (2) interim REI's that are longer than those that would be established under the WPS.

The WPS prohibits routine entry to perform hand labor tasks during the REI and requires PPE to be worn for other early-entry tasks that require contact with treated surfaces.

"Double" notification is the statement on the labels of some WPS pesticide products requiring employers to notify workers about pesticide-treated areas orally as well as by posting of the treated areas. The interim WPS "double" notification requirement was imposed if the active ingredient is classified as toxicity category I for acute dermal toxicity or skin irritation potential.

During the reregistration process, EPA establishes REI's, early-entry PPE, and double notification requirements based on consideration of all available relevant information about the active ingredient, including acute toxicity, other adverse effects, epidemiological information, and post-application data. Since the Agency has determined that the heptanoate ester is toxicologically equivalent to the octanoate ester, the WPS entry restrictions established here also apply to end-use products containing the heptanoate ester.

Restricted-entry intervals: EPA is establishing a 24-hour REI for all uses of bromoxynil other than cotton and turf grown for transplanting (e.g., on sod farms). The basis for this decision is the classification of bromoxynil as toxicity category II for eye irritation potential and concerns about risks due to developmental effects and cancer effects resulting from post-application activities in crops such as corn and small grains. The application timing for such crops, which comprise approximately 90% of bromoxynil usage, is early in the season (from preemergence to prior to tassel emergence/boot stage). Because of the use patterns and mode of action of bromoxynil, most workers entering treated fields would likely be performing scouting tasks or low contact labor tasks such as mechanical incorporation and cultivation. In these situations, the risks to post-application workers should be acceptable at 24 hours following application.

Since the toxicological endpoint for short-term and intermediate-term exposure is based on a NOEL for developmental effects, EPA is concerned that the default REI of 24 hours is not protective for cotton workers and sod harvesters where there is significant potential for postapplication exposures. The window of application for transgenic cotton is wider, which increases the potential for worker

contact with treated surfaces. In addition, cotton crops are scouted frequently leading to more opportunities for exposure than for the corn and small grain crops. Commercially grown sod may be harvested soon after an application, which could result in relatively high post-application exposures to workers and to exposures to persons at residential sites. Based on these concerns and a surrogate post-application exposure and risk assessment, EPA is establishing a 4-day REI for uses of bromoxynil on cotton and a 26-day REI for uses of bromoxynil on turf grown for transplanting (e.g., on sod farms). EPA believes that measures to reduce short- and intermediate-term risks also will reduce cancer risks. These REIs reconfirm the REIs of 4 days for cotton and 26 days for sod established in the Federal Register Notice published May 13, 1998, in conjunction with the cotton use registration action.

Early-Entry PPE: The WPS prohibits routine entry to perform hand labor tasks during the REI and requires PPE to be worn for other early-entry tasks that require contact with treated surfaces. As the result of Agency concerns about risks due to developmental effects and cancer effects resulting from post-application activities, EPA is requiring the following early-entry PPE for all in-scope WPS uses of products containing bromoxynil: coveralls, shoes plus socks, and chemical-resistant gloves. In addition, protective eyewear is required, because bromoxynil is classified as category II for eye irritation potential

"Double" Notification: "Double" notification is the statement on the labels of some WPS pesticide products requiring employers to notify workers about pesticide-treated areas orally as well as by posting of the treated areas. The interim WPS "double" notification requirement was imposed if the active ingredient is classified as toxicity category I for acute dermal toxicity or skin irritation potential. EPA has determined that double notification is required for uses of bromoxynil on cotton and on turf grown for transplanting because of Agency concerns about developmental effects and the possibility of inadvertent entry following uses at these sites.

b. Occupational-Use Products (NonWPS Uses)

Since EPA has concerns about post-application exposures to persons after nonWPS occupational uses of bromoxynil, it is establishing entry restrictions for all nonWPS occupational uses. However, since the anticipated frequency, duration, and degree of exposure following nonWPS occupational applications do not warrant a 24-hour entry restriction, the Agency is restricting entry into treated areas after such applications only until sprays have dried.

C. Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing bromoxynil. For the specific labeling statements, refer to Section V of this document.

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of bromoxynil for the above eligible uses has been reviewed and determined to be substantially complete. However, additional confirmatory data are needed to fulfill requirements for the guidelines listed below:

- Aquatic Plant Toxicity (*Anabaena flos-aquae* and *Lemna gibba*)
- Chronic Estuarine/Marine Fish and Invertebrates

The Agency also does not have acute toxicity information for a bromoxynil technical product and is requesting that that information be supplied to the Agency. Specific data requirements are listed in Appendix G.

Additionally, in order to allow more precise estimates of exposure to bromoxynil in drinking water, the Agency herein reiterates the requirement of the submission of an acceptable surface water monitoring program as specified in the FR Notice, 63FR26473.

2. Labeling Requirements for Manufacturing-Use Products

a. Formulation Statements

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions for Use:

"Only for formulation into an herbicide for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under "Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

(a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

(b) "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

b. Plantback Intervals

A 30-day plantback interval (PBI) is required for all crops except cotton. For cotton required additional limited field rotational crop studies have not been submitted to the Agency; acceptable studies previously submitted in support of reregistration reflect a maximum seasonal and single application rate of 0.5 lb ai/A, but the use on cotton constitutes a maximum seasonal application rate of 1.5 lb ai/A. Pending receipt of these studies registered labels must restrict rotation of treated cotton fields treated with more than 0.5 a.i./A/season to BXN cotton.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

Worker Protection Standard: The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10 and other applicable notices.

a. PPE/Engineering Control Requirements for Pesticide Handlers

For **sole-active-ingredient** end-use products that contain bromoxynil (including end-use products that contain the octanoic acid ester, the heptanoic acid ester, or a combination of the two esters):

- **!** Revise the product labeling to adopt the handler personal protective equipment/ engineering control requirements set forth in this section.
- **!** Remove any conflicting PPE requirements on the current labeling.

For **multiple-active-ingredient** end-use products that contain bromoxynil:

- **!** Compare the handler personal protective equipment/engineering control requirements set forth in this section to the requirements on the current labeling.
- **!** Retain the more protective requirements. (For guidance on which requirements are considered more protective, see PR Notice 93-7.)

b. Products Intended Primarily for Occupational Use (WPS and nonWPS)

(Note that this reregistration action is not intended to serve as the reregistraton action required for the heptanoic ester. However, because the heptanoic form is included in two labels with the octanoic ester form, the Agency is acting to correct the combined labels).

Active-Ingredient Specific Engineering Control Requirements

EPA is not establishing active-ingredient specific controls for occupational uses of bromoxynil end-use products, because all MOEs and cancer risk estimates for handlers were acceptable at baseline or with additional PPE, .

Active-Ingredient Specific Personal Protective Equipment Requirements

EPA is establishing the following active-ingredient-specific PPE for occupational uses of bromoxynil end-use products.

"Applicators and other handlers must wear:
-- long-sleeved shirt and long pants,
-- shoes plus socks,
--chemical-resistant gloves* for cleaning, equipment, mixing and loading,
--chemical-resistant apron for cleaning equipment, mixing, and loading."

*For the glove statement, use the statement established for bromoxynil through the instructions in Supplement Three of PR Notice 93-7.

Determining PPE Labeling Requirements for End-use Products Containing This Active Ingredient

The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient specific personal protective equipment specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7. If the acute inhalation toxicity of the bromoxynil **end-use product** is in category I or II, making a respirator necessary for pesticide handlers, the following type of respirator is appropriate: A dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C).

Placement in Labeling

The personal protective equipment requirements must be placed on the end-use product labeling in the location specified in PR Notice 93-7, and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

c. Entry Restrictions

For **sole-active-ingredient** end-use products that contain bromoxynil, including end-use products that contain the octanoic acid ester, the heptanoic acid ester, or a combination of the two esters: revise the product labeling to adopt the entry restrictions set forth in this section; and remove any conflicting entry restrictions on the current labeling.

For **multiple-active-ingredient** end-use products that contain bromoxynil:
compare the entry restrictions set forth in this section to the entry restrictions on the current labeling; and retain the more protective restrictions. (A specific time period in hours or days is considered more protective than "sprays have dried" or "dusts have settled.")

3. Products Intended Primarily for Occupational Use

a. WPS Uses

(1) Restricted-entry interval:

With the exception of cotton and turf grown for transplanting (e.g., on sod farms), a 24-hour restricted-entry interval (REI) is required for uses, within the scope of the WPS on all bromoxynil end-use products. The REI for cotton is 4 days and the REI for turf grown for transplanting (e.g., on sod farms) is 26 days. The exact wording of the restricted-entry interval for cotton must be as follows:

"The restricted-entry interval (REI) for cotton is 4 days and includes scouts and crop advisors. The exemption in the Worker Protection Standard for certified crop advisors does not apply to bromoxynil. Scouts and crop advisors are prohibited from entering the treated area during the entire 4-day REI for bromoxynil. Applicators and other users must inform crop advisors and scouts of this requirement."

(2) Early-entry personal protective equipment (PPE):

The PPE required for early entry is:
-- coveralls,
-- chemical-resistant gloves,
-- shoes plus socks, and
-- protective eyewear.

(3) WPS notification statement:

The following statement must be added to all end-use product labeling that contains directions for cotton or turf grown for transplanting (e.g., on sod farms):

> "For uses on cotton or on turf grown for transplanting (e.g., on sod farms): notify workers of the application by warning them orally <u>and</u> by posting warning signs at entrances to treated areas."

(4) Placement in labeling:

The REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7.

The PPE required for early entry must be inserted into the standardized early-entry PPE statement required by Supplement Three of PR Notice 93-7.

b. Non-WPS Uses

(1) Entry restrictions: the Agency is establishing the following entry restrictions for nonWPS occupational uses of bromoxynil end-use products: "Do not enter or allow others to enter the treated area until sprays have dried."

(2) Placement in labeling: If WPS uses are also on label -- Follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box, and place the appropriate nonWPS entry restrictions in that box. If no WPS uses are on the label -- Place the appropriate nonWPS entry restrictions in the Directions for Use, under the heading "Entry Restrictions."

4. Labeling for Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing bromoxynil that are intended primarily for occupational use:

a. Application Restrictions

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

"Aerial application is prohibited within 300 feet of residential areas (e.g., homes, schools, playgrounds, shopping areas, hospitals, etc.)."

"Apply to non-residential turf only. Do not apply to residential, playground, or schoolyard turf."

"Do not apply with backpack or hand-held application equipment."

"Application by chemigation must be done by fixed pipe, overhead sprinkler systems or hand-moved pipe. If hand-moved pipe is used, for chemigation, the pipe must not be handled in any way until 24 hours after chemigation has been completed and

residues have been flushed from the system. When applying by chemigation, no person may enter the application site during the chemigation unless in an enclosed vehicle."

b. Engineering Controls

Place the following user safety requirements immediately following the personal protective equipment and engineering control requirements:

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

c. User Safety Requirements

Place the following user safety requirements immediately following the engineering control statement above. The heading "user safety requirements" is not required -- just the following statements:

"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

"To reduce exposure to residues, wash the spray rig, tractor, and all other equipment used to handle or apply this product with water daily or before using the equipment for any other purpose."

5. User Safety Recommendations

Place the following user safety *recommendations* inside a box with the heading "User Safety Recommendations." The box must be located on the labeling immediately following the user safety *requirements* listed above.

"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10 and other applicable notices.

a. Spray Drift Labeling

The following language must be placed on each product label that can be applied aerially:

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions.

The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations.

1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.

2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.

Where states have more stringent regulations, they should be observed.

The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information.

The following aerial drift reduction advisory information must be contained in the product labeling:

[The section is advisory in nature and does not supersede the mandatory label requirements.]

INFORMATION ON DROPLET SIZE

The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions).

CONTROLLING DROPLET SIZE

! Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

! Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

! Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.

! Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.

! Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.

BOOM LENGTH

For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.

APPLICATION HEIGHT

Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

SWATH ADJUSTMENT

When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase with increasing drift potential (higher wind, smaller drops, etc.)

WIND

Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided at wind speeds below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

TEMPERATURE AND HUMIDITY

When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

TEMPERATURE INVERSIONS

Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by observing the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

SENSITIVE AREAS

The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell bromoxynil products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
ALFALFA				Use Group: TERRESTRIAL FEED CROP									
Broadcast, Seedling stage, Ground	EC	NA	.375 lb (AE) A	* NS	NS		.5 lb (AE)		NS	NS	0.5 d		C92, CAL, G01(60), G83(60)
	EC	NA	UC	* NS	NS		UC		NS	NS	0.5 d		C92, CAL, G01(60), G83(60)
Chemigation, Seedling stage, Center pivot irrigation	EC	NA	UC	* NS	NS		UC		NS	NS	0.5 d		C92, CAL, G01(60), G83(60)
Chemigation, Seedling stage, Hand move irrigation	EC	NA	UC	* NS	NS		UC		NS	NS	0.5 d		C92, CAL, G01(60), G83(60)
Chemigation, Seedling stage, Moving wheel irrigation	EC	NA	UC	* NS	NS		UC		NS	NS	0.5 d		C92, CAL, G01(60), G83(60)
Chemigation, Seedling stage, Solid set irrigation	EC	NA	UC	* NS	NS		UC		NS	NS	0.5 d		C92, CAL, G01(60), G83(60)
Chemigation, Seedling stage, Sprinkler irrigation	EC	NA	.5 lb (AE) A	* NS	NS		.5 lb (AE)		NS	NS	0.5 d		C92, CAL, G01(60), G83(60)
Low volume spray (concentrate), Seedling stage, Aircraft	EC	NA	.375 lb (AE) A	* NS	NS		.5 lb (AE)		NS	NS	0.5 d		C92, CAL, CSA(10), G01(60), G83(60)
	EC	NA	UC	* NS	NS		UC		NS	NS	0.5 d		C92, CAL, CSA(10), G01(60), G83(60)
Spray, Seedling stage, Aircraft	SC/L	NA	UC	* NS	NS		UC		NS	NS	0.5 d	CA	C92, CAL, CSA(10), G01(60), G83(60)
Spray, Seedling stage, Ground	SC/L	NA	UC	* NS	NS		UC		NS	NS	0.5 d	CA	C92, CAL, G01(60), G83(60)
BARLEY				Use Group: TERRESTRIAL FOOD+FEED CROP									
Broadcast, Postemergence, Ground	EC	NA	UC .5 lb (AE) A	* NS	NS		NS		NS	NS	0.5 d		C92, CAL, G01(30)

The uses listed in Appendix A were evaluated for reregistration. The following uses do not include any changes to use patterns, such as application rates or frequency, that may be mandated by this RED document.

FOOD/FEED USES

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
BARLEY (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)										
	EC	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GN5
Chemigation, Postemergence, Center pivot irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Hand move irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GC1
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Solid set irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Sprinkler irrigation	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
	EC	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GN5
	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10), GC1
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10), G01(30)
	EC	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10), GN5
	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Spray, Postemergence, Aircraft	FM/L	NA	UC	*	NS	NS	NS	NS	NS	NS			CAC
	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d		CA	C92, CAL, CSA(10), G01(30)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
BARLEY (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)										
	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10), GC1
Spray, Postemergence, Ground	FM/L	NA	UC	*	NS	NS	NS	NS	NS	NS			CAC
	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, G01(30)
	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GC1
CORN, FIELD			Use Group: TERRESTRIAL FOOD+FEED CROP										
Broadcast, Postemergence, Boom sprayer	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	12 h			C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Broadcast, Postemergence, Ground	EC	NA	.5 lb (AE) A	*	2	NS	.5 lb (AE)	NS	7	0.5 d			C92, CAL, G01(30), G83(30)
	EC	NA	UC	*	2	NS	UC	NS	7	0.5 d			C92, CAL, G01(30), G83(30)
Broadcast, Preemergence, Boom sprayer	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	12 h			C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Broadcast, Preemergence, Ground	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	0.5 d	CA		C92, CAL, G01(30), G83(30)
	EC	NA	UC	*	NS	NS	UC	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Broadcast, Preplant, Boom sprayer	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	12 h			C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Broadcast, Preplant, Ground	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	0.5 d	CA		C92, CAL, G01(30), G83(30)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
CORN, FIELD (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)								
	EC	NA	UC	*	NS NS	UC	NS	NS	0.5 d		C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Center pivot irrigation	EC	NA	UC	*	NS NS	UC	NS	NS	0.5 d		C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Hand move irrigation	EC	NA	UC	*	NS NS	UC	NS	NS	0.5 d		C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	UC	*	NS NS	UC	NS	NS	0.5 d		C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Solid set irrigation	EC	NA	UC	*	NS NS	UC	NS	NS	0.5 d		C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Sprinkler irrigation	EC	NA	.5 lb (AE) A	*	2 NS	.5 lb (AE)	NS	7	0.5 d	CA	C92, CAL, G01(30), G83(30)
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.5 lb (AE) A	*	2 NS	.5 lb (AE)	NS	7	0.5 d		C92, CAL, CSA(10), G01(30), G83(30)
	EC	NA	UC	*	2 NS	UC	NS	7	0.5 d		C92, CAL, G01(30), G83(30)
	EC	NA	.375 lb (AE) A	*	NS NS	.5 lb (AE)	NS	NS	12 h		C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
	FM/L	NA	.375 lb (AE) A	*	2 NS	.75 lb (AE)	NS	NS	12 h		C46, C92, CWE, CWH, CWL, G01(30), G83(30)
Low volume spray (concentrate), Postemergence, Low volume ground sprayer	EC	NA	.375 lb (AE) A	*	NS NS	.5 lb (AE)	NS	NS	12 h		C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
CORN, FIELD (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)									
Low volume spray (concentrate), Preemergence, Aircraft	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)		NS	NS	0.5 d	CA	C92, CAL, CSA(10), G01(30), G83(30)
	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)		NS	NS	12 h		C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
	EC	NA	UC	*	NS	NS	UC		NS	NS	0.5 d		C92, CAL, CSA(10), G01(30), G83(30)
	FM/L	NA	.375 lb (AE) A	*	2	NS	.75 lb (AE)		NS	NS	12 h		C46, C92, CWE, CWH, CWL, G01(30), G83(30)
Low volume spray (concentrate), Preemergence, Low volume ground sprayer	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)		NS	NS	12 h		C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Low volume spray (concentrate), Preplant, Aircraft	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)		NS	NS	0.5 d	CA	C92, CAL, CSA(10), G01(30), G83(30)
	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)		NS	NS	12 h		C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
	EC	NA	UC	*	NS	NS	UC		NS	NS	0.5 d		C92, CAL, CSA(10), G01(30), G83(30)
	FM/L	NA	.375 lb (AE) A	*	2	NS	.75 lb (AE)		NS	NS	12 h		C46, C92, CWE, CWH, CWL, G01(30), G83(30)
Low volume spray (concentrate), Preplant, Low volume ground sprayer	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)		NS	NS	12 h		C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Dose	# Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
CORN, FIELD (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)										
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	2	NS	UC	NS	7	0.5 d	CA		C92, CAL, CSA(10), GN6
Spray, Postemergence, Boom sprayer	FM/L	NA	.375 lb (AE) A	*	2	NS	.75 lb (AE)	NS	NS	12 h			C46, C92, CWE, CWH, CWL, G01(30), G83(30)
Spray, Postemergence, Ground	SC/L	NA	UC	*	2	NS	UC	NS	7	0.5 d	CA		C92, CAL, GN6
Spray, Postemergence, Sprayer	EC	NA	UC	*	2	NS	UC	NS	NS	12 h			C46, C92, CCB, CWE, CWL, G01(45), G83(45)
	WP	NA	UC	*	NS	NS	NS	NS	NS	12 h			C46, C92, CCB, CWE, CWH, CWL
Spray, Preemergence, Aircraft	EC	NA	UC	*	2	NS	UC	NS	NS	12 h			C46, C92, CCB, CSA(10), CWE, CWL, G01(45), G83(45)
	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, CSA(10), GN6
Spray, Preemergence, Boom sprayer	FM/L	NA	.375 lb (AE) A	*	2	NS	.75 lb (AE)	NS	NS	12 h			C46, C92, CWE, CWH, CWL, G01(30), G83(30)
Spray, Preemergence, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, GN6
Spray, Preemergence, Sprayer	EC	NA	UC	*	2	NS	UC	NS	NS	12 h			C46, C92, CCB, CWE, CWL, G01(45), G83(45)
	WP	NA	UC	*	NS	NS	NS	NS	NS	12 h			C46, C92, CCB, CWE, CWH, CWL

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop	/year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
CORN, FIELD (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)										
Spray, Preplant, Boom sprayer	FM/L	NA	.375 lb (AE) A	*	2	NS	.75 lb (AE)	NS	NS	12 h			C46, C92, CWE, CWH, CWL, G01(30), G83(30)
CORN, POP			Use Group: TERRESTRIAL FOOD+FEED CROP										
Broadcast, Postemergence, Boom sprayer	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	12 h			C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Broadcast, Postemergence, Ground	EC	NA	.375 lb (AE) A	*	2	NS	.5 lb (AE)	NS	7	0.5 d			C92, CAL, G01(30), G83(30)
	EC	NA	UC	*	2	NS	UC	NS	7	0.5 d			C92, CAL, G01(30), G83(30)
Broadcast, Preemergence, Boom sprayer	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	12 h			C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Broadcast, Preemergence, Ground	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	0.5 d		CA	C92, CAL, G01(30), G83(30)
	EC	NA	UC	*	NS	NS	UC	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Broadcast, Preplant, Boom sprayer	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	12 h			C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Broadcast, Preplant, Ground	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	0.5 d		CA	C92, CAL, G01(30), G83(30)
	EC	NA	UC	*	NS	NS	UC	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
CORN, POP (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)										
Chemigation, Postemergence, Center pivot irrigation	EC	NA	UC	*	NS	NS	UC	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Hand move irrigation	EC	NA	UC	*	NS	NS	UC	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	UC	*	NS	NS	UC	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Solid set irrigation	EC	NA	UC	*	NS	NS	UC	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Sprinkler irrigation	EC	NA	.5 lb (AE) A	*	2	NS	.5 lb (AE)	NS	7	0.5 d	CA		C92, CAL, G01(30), G83(30)
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.375 lb (AE) A	*	2	NS	.5 lb (AE)	NS	7	0.5 d			C92, CAL, CSA(10), G01(30), G83(30)
	EC	NA	UC	*	2	NS	UC	NS	7	0.5 d			C92, CAL, G01(30), G83(30)
	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	12 h			C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
	FM/L	NA	.375 lb (AE) A	*	2	NS	.75 lb (AE)	NS	NS	12 h			C46, C92, CWE, CWH, CWL, G01(30), G83(30)
Low volume spray (concentrate), Postemergence, Low volume ground sprayer	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	12 h			C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Low volume spray (concentrate), Preemergence, Aircraft	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	0.5 d	CA		C92, CAL, CSA(10), G01(30), G83(30)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Dose	Max. # Apps @ Max. Rate /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
CORN, POP (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)							
	EC	NA	.375 lb (AE) A	*	NS NS	.5 lb (AE)	NS	NS	12 h		C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
	EC	NA	UC	*	NS NS	UC	NS	NS	0.5 d		C92, CAL, CSA(10), G01(30), G83(30)
	FM/L	NA	.375 lb (AE) A	*	2 NS	.75 lb (AE)	NS	NS	12 h		C46, C92, CWE, CWH, CWL, G01(30), G83(30)
Low volume spray (concentrate), Preemergence, Low volume ground sprayer	EC	NA	.375 lb (AE) A	*	NS NS	.5 lb (AE)	NS	NS	12 h		C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Low volume spray (concentrate), Preplant, Aircraft	EC	NA	.375 lb (AE) A	*	NS NS	.5 lb (AE)	NS	NS	0.5 d	CA	C92, CAL, CSA(10), G01(30), G83(30)
	EC	NA	.375 lb (AE) A	*	NS NS	.5 lb (AE)	NS	NS	12 h		C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
	EC	NA	UC	*	NS NS	UC	NS	NS	0.5 d		C92, CAL, CSA(10), G01(30), G83(30)
	FM/L	NA	.375 lb (AE) A	*	2 NS	.75 lb (AE)	NS	NS	12 h		C46, C92, CWE, CWH, CWL, G01(30), G83(30)
Low volume spray (concentrate), Preplant, Low volume ground sprayer	EC	NA	.375 lb (AE) A	*	NS NS	.5 lb (AE)	NS	NS	12 h		C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	2 NS	UC	NS	7	0.5 d	CA	C92, CAL, CSA(10), GN6

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
CORN, POP (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)										
Spray, Postemergence, Boom sprayer	FM/L	NA	.375 lb (AE) A	*	2	NS	.75 lb (AE)	NS	NS	12 h			C46, C92, CWE, CWH, CWL, G01(30), G83(30)
Spray, Postemergence, Ground	SC/L	NA	UC	*	2	NS	UC	NS	7	0.5 d		CA	C92, CAL, GN6
Spray, Postemergence, Sprayer	EC	NA	UC	*	2	NS	UC	NS	NS	12 h			C46, C92, CCB, CWE, CWL, G01(45), G83(45)
	WP	NA	UC	*	NS	NS	NS	NS	NS	12 h			C46, C92, CCB, CWE, CWH, CWL
Spray, Preemergence, Aircraft	EC	NA	UC	*	2	NS	UC	NS	NS	12 h			C46, C92, CCB, CSA(10), CWE, CWL, G01(45), G83(45)
	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d		CA	C92, CAL, CSA(10), GN6
Spray, Preemergence, Boom sprayer	FM/L	NA	.375 lb (AE) A	*	2	NS	.75 lb (AE)	NS	NS	12 h			C46, C92, CWE, CWH, CWL, G01(30), G83(30)
Spray, Preemergence, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d		CA	C92, CAL, GN6
Spray, Preemergence, Sprayer	EC	NA	UC	*	2	NS	UC	NS	NS	12 h			C46, C92, CCB, CWE, CWL, G01(45), G83(45)
	WP	NA	UC	*	NS	NS	NS	NS	NS	12 h			C46, C92, CCB, CWE, CWH, CWL
Spray, Preplant, Boom sprayer	FM/L	NA	.375 lb (AE) A	*	2	NS	.75 lb (AE)	NS	NS	12 h			C46, C92, CWE, CWH, CWL, G01(30), G83(30)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
CORN, SWEET				Use Group: TERRESTRIAL FOOD+FEED CROP							
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA	C92, CAL, CSA(10), GN6
Spray, Postemergence, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA	C92, CAL, GN6
Spray, Preemergence, Aircraft	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA	C92, CAL, CSA(10), GN6
Spray, Preemergence, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA	C92, CAL, GN6
COTTON (UNSPECIFIED)				Use Group: TERRESTRIAL FOOD+FEED CROP							
Band treatment, Postemergence, Ground	EC	NA	.5 lb (AE) A	*	3	NS	1.5 lb (AE)	NS	NS	0.5 d	CA	C92, CAL, GP1, H01(60)
	EC	NA	UC	*	3	NS	UC	NS	NS	0.5 d		C92, CAL, GC1, GO3, H01(60)
Band treatment, Preemergence, Ground	EC	NA	.5 lb (AE) A	*	NS	NS	1.5 lb (AE)	NS	NS	0.5 d	CA	C92, CAL, GP1, H01(60)
	EC	NA	UC	*	NS	NS	UC	NS	NS	0.5 d		C92, CAL, GC1, GO3, H01(60)
Band treatment, Preplant, Ground	EC	NA	.5 lb (AE) A	*	NS	NS	1.5 lb (AE)	NS	NS	0.5 d	CA	C92, CAL, GP1, H01(60)
	EC	NA	UC	*	NS	NS	UC	NS	NS	0.5 d		C92, CAL, GC1, GO3, H01(60)
Broadcast, Postemergence, Ground	EC	NA	.5 lb (AE) A	*	3	NS	1.5 lb (AE)	NS	NS	0.5 d	CA	C92, CAL, GP1, H01(60)
	EC	NA	UC	*	3	NS	UC	NS	NS	0.5 d		C92, CAL, GC1, GO3, H01(60)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Tex.	# Apps Max. @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
COTTON (UNSPECIFIED) (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)										
Broadcast, Preemergence, Ground	EC	NA	.5 lb (AE) A	*	NS	NS	1.5 lb (AE)		NS	NS	0.5 d	CA	C92, CAL, GP1, H01(60)
	EC	NA	UC	*	NS	NS	UC		NS	NS	0.5 d		C92, CAL, GC1, GO3, H01(60)
Broadcast, Preplant, Ground	EC	NA	.5 lb (AE) A	*	NS	NS	1.5 lb (AE)		NS	NS	0.5 d	CA	C92, CAL, GP1, H01(60)
	EC	NA	UC	*	NS	NS	UC		NS	NS	0.5 d		C92, CAL, GC1, GO3, H01(60)
FLAX			Use Group: TERRESTRIAL FOOD+FEED CROP										
Broadcast, Postemergence, Ground	EC	NA	UC .25 lb (AE) A	*	NS	NS	NS		NS	NS	0.5 d		C92, CAL
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	UC	*	NS	NS	NS		NS	NS	0.5 d		C92, CAL
	EC	NA	.25 lb (AE) A	*	NS	NS	NS		NS	NS	0.5 d		C92, CAL, CSA(10)
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	NS	NS	NS		NS	NS	0.5 d	CA	C92, CAL, CSA(10)
Spray, Postemergence, Ground	SC/L	NA	UC	*	NS	NS	NS		NS	NS	0.5 d	CA	C92, CAL
GARLIC			Use Group: TERRESTRIAL FOOD CROP										
Broadcast, Postemergence, Ground	EC	NA	UC .5 lb (AE) A	*	NS	NS	NS		NS	NS	0.5 d		C92, CAL, H01(112)
Chemigation, Postemergence, Center pivot irrigation	EC	NA	UC	*	NS	NS	NS		NS	NS	0.5 d		C92, CAL, H01(112)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year Max. Dose /crop cycle	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
GARLIC (con't)				Use Group: TERRESTRIAL FOOD CROP (con't)								
Chemigation, Postemergence, Hand move irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, H01(112)
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, H01(112)
Chemigation, Postemergence, Solid set irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, H01(112)
Chemigation, Postemergence, Sprinkler irrigation	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, H01(112)
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	UC .5 lb (AE) A	* *	NS	NS	NS	NS	NS	0.5 d		C92, CAL, H01(112)
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d	CA	C92, CAL, H01(112)
Spray, Postemergence, Ground	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d	CA	C92, CAL, H01(112)
MILLET (PROSO)				Use Group: TERRESTRIAL FEED CROP								
Broadcast, Postemergence, Ground	EC	NA	.375 lb (AE) A	*	NS	NS	NS	NS	NS	NS	WI	
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.375 lb (AE) A	*	NS	NS	NS	NS	NS	NS	WI	
OATS				Use Group: TERRESTRIAL FOOD+FEED CROP								
Broadcast, Postemergence, Ground	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, G01(30)
	EC	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, GN5
	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d	OR, WA, CO, WY, MT	C92, CAL, G01(30)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
OATS (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)								
Chemigation, Postemergence, Center pivot irrigation	EC	NA	UC	*	NS	NS	NS	NS	0.5 d	OR, WA, CO, WY, MT	C92, CAL, G01(30)
Chemigation, Postemergence, Hand move irrigation	EC	NA	UC	*	NS	NS	NS	NS	0.5 d	OR, WA, CO, WY, MT	C92, CAL, G01(30)
	SC/L	NA	UC	*	NS	NS	NS	NS	0.5 d		C92, CAL, G01(30)
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	UC	*	NS	NS	NS	NS	0.5 d	OR, WA, CO, WY, MT	C92, CAL, G01(30)
Chemigation, Postemergence, Solid set irrigation	EC	NA	UC	*	NS	NS	NS	NS	0.5 d	OR, WA, CO, WY, MT	C92, CAL, G01(30)
Chemigation, Postemergence, Sprinkler irrigation	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	0.5 d		C92, CAL, G01(30)
	EC	NA	1 lb (AE) A	*	NS	NS	NS	NS	0.5 d		C92, CAL, GN5
	SC/L	NA	UC	*	NS	NS	NS	NS	0.5 d		C92, CAL, G01(30)
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	0.5 d		C92, CAL, CSA(10), G01(30)
	EC	NA	1 lb (AE) A	*	NS	NS	NS	NS	0.5 d		C92, CAL, CSA(10), GN5
	EC	NA	UC	*	NS	NS	NS	NS	0.5 d	OR, WA, CO, WY, MT	C92, CAL, G01(30)
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	NS	NS	UC	NS	0.5 d	CA	C92, CAL, CSA(10), G01(30)
	SC/L	NA	UC	*	NS	NS	NS	NS	0.5 d		C92, CAL, CSA(10), G01(30)
Spray, Postemergence, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	0.5 d	CA	C92, CAL, G01(30)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
OATS (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)									
	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
ONION				Use Group: TERRESTRIAL FOOD CROP									
Broadcast, Postemergence, Ground	EC	NA	UC .375 lb (AE) A	* *	NS	NS	NS	NS	NS	0.5 d			C92, CAL
Broadcast, Preemergence, Ground	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL
	EC	NA	.375 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d	012		C92, CAL
Broadcast, Preplant, Ground	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL
Chemigation, Postemergence, Center pivot irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL
Chemigation, Postemergence, Hand move irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL
Chemigation, Postemergence, Solid set irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL
Chemigation, Postemergence, Sprinkler irrigation	EC	NA	.375 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL
Low volume spray (concentrate), Preemergence, Aircraft	EC	NA	.375 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d	012		C92, CAL, CSA(10)
Spray, Postemergence, Ground	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		CA	C92, CAL
Spray, Preemergence, Aircraft	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		CA, 011	C92, CAL, CSA(10)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
ONION (con't)				Use Group: TERRESTRIAL FOOD CROP (con't)									
Spray, Preemergence, Ground	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d	CA, 011		C92, CAL
PEPPERMINT				Use Group: TERRESTRIAL FOOD+FEED CROP									
Broadcast, Dormant, Ground	EC	NA	.375 lb (AE) A	*	NS	NS	1.5 lb (AE)	NS	NS	0.5 d	CA		C92, CAL, H01(70)
	EC	NA	UC	*	NS	NS	UC	NS	NS	0.5 d			C92, CAL, H01(70)
Broadcast, Established plantings, Ground	EC	NA	.375 lb (AE) A	*	NS	NS	1.5 lb (AE)	NS	NS	0.5 d	CA		C92, CAL, H01(70)
	EC	NA	UC	*	NS	NS	UC	NS	NS	0.5 d			C92, CAL, H01(70)
Chemigation, Dormant, Sprinkler irrigation	EC	NA	.375 lb (AE) A	*	NS	NS	1.5 lb (AE)	NS	NS	0.5 d	CA		C92, CAL, H01(70)
Chemigation, Established plantings, Sprinkler irrigation	EC	NA	.375 lb (AE) A	*	NS	NS	1.5 lb (AE)	NS	NS	0.5 d	CA		C92, CAL, H01(70)
Spray, Dormant, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, H01(70)
Spray, Established plantings, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, H01(70)
RYE				Use Group: TERRESTRIAL FOOD+FEED CROP									
Broadcast, Postemergence, Ground	EC	NA	UC .5 lb (AE) A	* *	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
	EC	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GN5
Chemigation, Postemergence, Center pivot irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Hand move irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
RYE (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)									
	SC/L	NA	UC	*	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	UC	*	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Solid set irrigation	EC	NA	UC	*	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Sprinkler irrigation	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
	EC	NA	1 lb (AE) A	*	NS	NS	NS	NS	0.5 d			C92, CAL, GN5
	SC/L	NA	UC	*	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10), G01(30)
	EC	NA	1 lb (AE) A	*	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10), GN5
	EC	NA	UC	*	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	NS	NS	UC	NS	0.5 d	CA		C92, CAL, CSA(10), G01(30)
	SC/L	NA	UC	*	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10), G01(30)
Spray, Postemergence, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	0.5 d	CA		C92, CAL, G01(30)
	SC/L	NA	UC	*	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
SORGHUM			Use Group: TERRESTRIAL FEED CROP									

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
SORGHUM (con't)			Use Group: TERRESTRIAL FEED CROP (con't)										
Broadcast, Postemergence, Boom sprayer	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	12 h			C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Broadcast, Postemergence, Ground	EC	NA	.375 lb (AE) A	*	2	NS	.5 lb (AE)	NS	7	0.5 d			C92, CAL, G01(30), G83(30)
	EC	NA	UC	*	2	NS	UC	NS	7	0.5 d			C92, CAL, G01(30), G83(30)
Broadcast, Preemergence, Boom sprayer	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	12 h			C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Broadcast, Preemergence, Ground	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	0.5 d	CA		C92, CAL, G01(30), G83(30)
	EC	NA	UC	*	NS	NS	UC	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Broadcast, Preplant, Boom sprayer	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	12 h			C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Broadcast, Preplant, Ground	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	0.5 d	CA		C92, CAL, G01(30), G83(30)
	EC	NA	UC	*	NS	NS	UC	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Center pivot irrigation	EC	NA	UC	*	NS	NS	UC	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Hand move irrigation	EC	NA	UC	*	NS	NS	UC	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
SORGHUM (con't)				Use Group: TERRESTRIAL FEED CROP (con't)									
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	UC	*	NS	NS	UC	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Solid set irrigation	EC	NA	UC	*	NS	NS	UC	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Sprinkler irrigation	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	7	0.5 d			C92, CAL, G01(30), G83(30)
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.375 lb (AE) A	*	2	NS	.5 lb (AE)	NS	7	0.5 d	CA		C92, CAL, CSA(10), G01(30), G83(30)
	EC	NA	UC	*	2	NS	UC	NS	7	0.5 d			C92, CAL, G01(30), G83(30)
	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	12 h			C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
	FM/L	NA	.375 lb (AE) A	*	2	NS	.75 lb (AE)	NS	NS	12 h			C46, C92, CWE, CWH, CWL, G01(30), G83(30)
Low volume spray (concentrate), Postemergence, Low volume ground sprayer	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	12 h			C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Low volume spray (concentrate), Preemergence, Aircraft	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	0.5 d	CA		C92, CAL, CSA(10), G01(30), G83(30)
	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	12 h			C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
	EC	NA	UC	*	NS	NS	UC	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
SORGHUM (con't)			Use Group: TERRESTRIAL FEED CROP (con't)										
	FM/L	NA	.375 lb (AE) A	*	2	NS	.75 lb (AE)		NS	NS	12 h		C46, C92, CWE, CWH, CWL, G01(30), G83(30)
Low volume spray (concentrate), Preemergence, Low volume ground sprayer	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)		NS	NS	12 h		C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Low volume spray (concentrate), Preplant, Aircraft	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)		NS	NS	0.5 d	CA	C92, CAL, CSA(10), G01(30), G83(30)
	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)		NS	NS	12 h		C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
	EC	NA	UC	*	NS	NS	UC		NS	NS	0.5 d		C92, CAL, G01(30), G83(30)
	FM/L	NA	.375 lb (AE) A	*	2	NS	.75 lb (AE)		NS	NS	12 h		C46, C92, CWE, CWH, CWL, G01(30), G83(30)
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	2	NS	UC		NS	7	0.5 d	CA	C92, CAL, CSA(10), GN6
Spray, Postemergence, Boom sprayer	FM/L	NA	.375 lb (AE) A	*	2	NS	.75 lb (AE)		NS	NS	12 h		C46, C92, CWE, CWH, CWL, G01(30), G83(30)
Spray, Postemergence, Ground	SC/L	NA	UC	*	2	NS	UC		NS	7	0.5 d	CA	C92, CAL, GN6
Spray, Postemergence, Sprayer	EC	NA	UC UC UC	* F M	2	NS	UC		NS	NS	12 h		C46, C92, CCB, CWE, CWL, G01(45), G83(45)
	WP	NA	UC	*	NS	NS	NS		NS	NS	12 h		C46, C92, CCB, CWE, CWH, CWL

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Tex.	# Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
SORGHUM (con't)			Use Group: TERRESTRIAL FEED CROP (con't)										
Spray, Preemergence, Aircraft	EC	NA	UC UC UC	* F M	2	NS	UC	NS	NS	12 h			C46, C92, CCB, CSA(10), CWE, CWL, G01(45), G83(45)
	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, CSA(10), GN6
Spray, Preemergence, Boom sprayer	FM/L	NA	.375 lb (AE) A	*	2	NS	.75 lb (AE)	NS	NS	12 h			C46, C92, CWE, CWH, CWL, G01(30), G83(30)
Spray, Preemergence, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, GN6
Spray, Preemergence, Sprayer	EC	NA	UC UC UC	* F M	2	NS	UC	NS	NS	12 h			C46, C92, CCB, CWE, CWL, G01(45), G83(45)
	WP	NA	UC	*	NS	NS	NS	NS	NS	12 h			C46, C92, CCB, CWE, CWH, CWL
Spray, Preplant, Boom sprayer	FM/L	NA	.375 lb (AE) A	*	2	NS	.75 lb (AE)	NS	NS	12 h			C46, C92, CWE, CWH, CWL, G01(30), G83(30)
			Use Group: TERRESTRIAL FOOD+FEED CROP										
Broadcast, Postemergence, Boom sprayer	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	12 h			C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Broadcast, Postemergence, Ground	EC	NA	.375 lb (AE) A	*	2	NS	.5 lb (AE)	NS	7	0.5 d			C92, CAL, G01(30), G83(30)
	EC	NA	UC	*	2	NS	UC	NS	7	0.5 d			C92, CAL, G01(30), G83(30)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
SORGHUM (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)										
Broadcast, Preemergence, Boom sprayer	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)		NS	12 h			C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Broadcast, Preemergence, Ground	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)		NS	0.5 d	CA		C92, CAL, G01(30), G83(30)
	EC	NA	UC	*	NS	NS	UC		NS	0.5 d			C92, CAL, G01(30), G83(30)
Broadcast, Preplant, Boom sprayer	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)		NS	12 h			C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Broadcast, Preplant, Ground	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)		NS	0.5 d	CA		C92, CAL, G01(30), G83(30)
	EC	NA	UC	*	NS	NS	UC		NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Center pivot irrigation	EC	NA	UC	*	NS	NS	UC		NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Hand move irrigation	EC	NA	UC	*	NS	NS	UC		NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	UC	*	NS	NS	UC		NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Solid set irrigation	EC	NA	UC	*	NS	NS	UC		NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Sprinkler irrigation	EC	NA	.5 lb (AE) A	*	NS	NS	NS		NS	7 0.5 d	CA		C92, CAL, G01(30), G83(30)
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.375 lb (AE) A	*	2	NS	.5 lb (AE)		NS	7 0.5 d			C92, CAL, CSA(10), G01(30), G83(30)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
SORGHUM (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)								
	EC	NA	UC	*	2	NS	UC	NS	7	0.5 d		C92, CAL, G01(30), G83(30)
	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	12 h		C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
	FM/L	NA	.375 lb (AE) A	*	2	NS	.75 lb (AE)	NS	NS	12 h		C46, C92, CWE, CWH, CWL, G01(30), G83(30)
Low volume spray (concentrate), Postemergence, Low volume ground sprayer	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	12 h		C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Low volume spray (concentrate), Preemergence, Aircraft	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	0.5 d	CA	C92, CAL, CSA(10), G01(30), G83(30)
	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	12 h		C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
	EC	NA	UC	*	NS	NS	UC	NS	NS	0.5 d		C92, CAL, CSA(10), G01(30), G83(30)
	FM/L	NA	.375 lb (AE) A	*	2	NS	.75 lb (AE)	NS	NS	12 h		C46, C92, CWE, CWH, CWL, G01(30), G83(30)
Low volume spray (concentrate), Preemergence, Low volume ground sprayer	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	12 h		C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Low volume spray (concentrate), Preplant, Aircraft	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)	NS	NS	0.5 d	CA	C92, CAL, CSA(10), G01(30), G83(30)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
SORGHUM (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)										
	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)		NS	NS	12 h		C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
	EC	NA	UC	*	NS	NS	UC		NS	NS	0.5 d		C92, CAL, CSA(10), G01(30), G83(30)
	FM/L	NA	.375 lb (AE) A	*	2	NS	.75 lb (AE)		NS	NS	12 h		C46, C92, CWE, CWH, CWL, G01(30), G83(30)
Low volume spray (concentrate), Preplant, Low volume ground sprayer	EC	NA	.375 lb (AE) A	*	NS	NS	.5 lb (AE)		NS	NS	12 h		C13, C46, C92, CCB, CWE, CWH, CWL, G01(45)
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	2	NS	UC		NS	7	0.5 d	CA	C92, CAL, CSA(10), GN6
Spray, Postemergence, Boom sprayer	FM/L	NA	.375 lb (AE) A	*	2	NS	.75 lb (AE)		NS	NS	12 h		C46, C92, CWE, CWH, CWL, G01(30), G83(30)
Spray, Postemergence, Ground	SC/L	NA	UC	*	2	NS	UC		NS	7	0.5 d	CA	C92, CAL, GN6
Spray, Postemergence, Sprayer	EC	NA	UC UC UC	* F M	2	NS	UC		NS	NS	12 h		C46, C92, CCB, CWE, CWL, G01(45), G83(45)
	WP	NA	UC	*	NS	NS	NS		NS	NS	12 h		C46, C92, CCB, CWE, CWH, CWL
Spray, Preemergence, Aircraft	EC	NA	UC UC UC	* F M	2	NS	UC		NS	NS	12 h		C46, C92, CCB, CSA(10), CWE, CWL, G01(45), G83(45)
	SC/L	NA	UC	*	NS	NS	UC		NS	NS	0.5 d	CA	C92, CAL, CSA(10), GN6

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
SORGHUM (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)								
Spray, Preemergence, Boom sprayer	FM/L	NA	.375 lb (AE) A	*	2	.75 lb (AE)	NS	NS	12 h		C46, C92, CWE, CWH, CWL, G01(30), G83(30)
Spray, Preemergence, Ground	SC/L	NA	UC	*	NS	UC	NS	NS	0.5 d	CA	C92, CAL, GN6
Spray, Preemergence, Sprayer	EC	NA	UC UC UC	* F M	2	UC	NS	NS	12 h		C46, C92, CCB, CWE, CWL, G01(45), G83(45)
	WP	NA	UC	*	NS	NS	NS	NS	12 h		C46, C92, CCB, CWE, CWH, CWL
Spray, Preplant, Boom sprayer	FM/L	NA	.375 lb (AE) A	*	2	.75 lb (AE)	NS	NS	12 h		C46, C92, CWE, CWH, CWL, G01(30), G83(30)
SPEARMINT			Use Group: TERRESTRIAL FOOD+FEED CROP								
Broadcast, Dormant, Ground	EC	NA	.375 lb (AE) A	*	NS	1.5 lb (AE)	NS	NS	0.5 d	CA	C92, CAL, H01(70)
	EC	NA	UC	*	NS	UC	NS	NS	0.5 d		C92, CAL, H01(70)
Broadcast, Established plantings, Ground	EC	NA	.375 lb (AE) A	*	NS	1.5 lb (AE)	NS	NS	0.5 d	CA	C92, CAL, H01(70)
	EC	NA	UC	*	NS	UC	NS	NS	0.5 d		C92, CAL, H01(70)
Chemigation, Dormant, Sprinkler irrigation	EC	NA	.375 lb (AE) A	*	NS	1.5 lb (AE)	NS	NS	0.5 d	CA	C92, CAL, H01(70)
Chemigation, Established plantings, Sprinkler irrigation	EC	NA	.375 lb (AE) A	*	NS	1.5 lb (AE)	NS	NS	0.5 d	CA	C92, CAL, H01(70)
Spray, Dormant, Ground	SC/L	NA	UC	*	NS	UC	NS	NS	0.5 d	CA	C92, CAL, H01(70)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
SPEARMINT (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)									
Spray, Established plantings, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, H01(70)
SUDANGRASS				Use Group: TERRESTRIAL FEED CROP									
Broadcast, Postemergence, Aircraft	EC	NA	.375 lb (AE) A	*	2	NS	.5 lb (AE)	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Broadcast, Postemergence, Ground	EC	NA	.375 lb (AE) A	*	2	NS	.5 lb (AE)	NS	7	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Sprinkler irrigation	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	7	0.5 d			C92, CAL, G01(30), G83(30)
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d	CA		C92, CAL, CSA(10)
Spray, Postemergence, Ground	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d	CA		C92, CAL
TRITICALE				Use Group: TERRESTRIAL FOOD CROP									
Broadcast, Postemergence, Ground	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Sprinkler irrigation	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10), G01(30)
				Use Group: TERRESTRIAL FOOD+FEED CROP									
Broadcast, Postemergence, Ground	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Center pivot irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Hand move irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
TRITICALE (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)									
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Solid set irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d		CA	C92, CAL, CSA(10), G01(30)
Spray, Postemergence, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d		CA	C92, CAL, G01(30)
WHEAT				Use Group: TERRESTRIAL FOOD+FEED CROP									
Broadcast, Postemergence, Ground	EC	NA	UC .5 lb (AE) A	* *	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
	EC	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GN5
Chemigation, Postemergence, Center pivot irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Hand move irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Solid set irrigation	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Sprinkler irrigation	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year Dose cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
WHEAT (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)									
	EC	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, GN5
	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, G01(30)
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, CSA(10), G01(30)
	EC	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, CSA(10), GN5
	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, G01(30)
Spray, Postemergence, Aircraft	FM/L	NA	UC	*	NS	NS	NS	NS	NS	NS		CAC
	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA	C92, CAL, CSA(10), G01(30)
	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, CSA(10), G01(30)
Spray, Postemergence, Ground	FM/L	NA	UC	*	NS	NS	NS	NS	NS	NS		CAC
	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA	C92, CAL, G01(30)
	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, G01(30)
NON-FOOD/NON-FEED												
AGRICULTURAL FALLOW/IDLELAND			Use Group: TERRESTRIAL NON-FOOD CROP									
Broadcast, Postemergence, Ground	EC	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d		C48, C92, CAL, G96
	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, GK3
	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d	CA	C92, CAL, GK3

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
AGRICULTURAL FALLOW/IDLELAND (con't)			Use Group: TERRESTRIAL NON-FOOD CROP (con't)										
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C48, C92, CAL, CSA(10), G96
	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GK3
	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d		CA	C92, CAL, GK3
Spray, When needed, Aircraft	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10), GK3
	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		CA	C92, CAL, CSA(10), GK3
Spray, When needed, Ground	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GK3
	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		CA	C92, CAL, GK3
COMMERCIAL/INDUSTRIAL LAWNS			Use Group: TERRESTRIAL NON-FOOD CROP										
Broadcast, Established plantings, Ground	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL
	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GK3
Broadcast, Preemergence, Ground	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL
	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GK3
Low volume spray (concentrate), Established plantings, Aircraft	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10)
	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10), GK3
Low volume spray (concentrate), Preemergence, Aircraft	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
COMMERCIAL/INDUSTRIAL LAWNS (con't)			Use Group: TERRESTRIAL NON-FOOD CROP (con't)										
	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10), GK3
Spray, Seedling stage, Aircraft	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		CA	C92, CAL, CSA(10)
Spray, Seedling stage, Ground	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		CA	C92, CAL
GOLF COURSE TURF			Use Group: TERRESTRIAL NON-FOOD CROP										
Broadcast, Established plantings, Ground	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL
	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GK3
Broadcast, Preemergence, Ground	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL
	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GK3
Low volume spray (concentrate), Established plantings, Aircraft	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10)
	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10), GK3
Low volume spray (concentrate), Preemergence, Aircraft	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10)
	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10), GK3
GRASSES GROWN FOR SEED			Use Group: TERRESTRIAL NON-FOOD CROP										
Broadcast, Established plantings, Ground	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G95
	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GK3
Broadcast, Postemergence, Ground	EC	NA	1 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G96

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
GRASSES GROWN FOR SEED (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)									
Broadcast, Preemergence, Ground	EC	NA		UC	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, G95
	EC	NA	.5 lb (AE) A		*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, GK3
Low volume spray (concentrate), Established plantings, Aircraft	EC	NA		UC	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, CSA(10), G95
	EC	NA	.5 lb (AE) A		*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, CSA(10), GK3
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	1 lb (AE) A		*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, CSA(10), G96
Low volume spray (concentrate), Preemergence, Aircraft	EC	NA		UC	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, CSA(10), G95
	EC	NA	.5 lb (AE) A		*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, CSA(10), GK3
Spray, Established plantings, Aircraft	SC/L	NA		UC	*	NS	NS	NS	NS	NS	0.5 d	CA	C92, CAL, CSA(10), GK3
Spray, Established plantings, Ground	SC/L	NA		UC	*	NS	NS	NS	NS	NS	0.5 d	CA	C92, CAL, GK3
Spray, Seedling stage, Aircraft	SC/L	NA		UC	*	NS	NS	NS	NS	NS	0.5 d	CA	C92, CAL, CSA(10), GK3
Spray, Seedling stage, Ground	SC/L	NA		UC	*	NS	NS	NS	NS	NS	0.5 d	CA	C92, CAL, GK3
INDUSTRIAL AREAS (OUTDOOR)				Use Group: TERRESTRIAL NON-FOOD CROP									
Broadcast, When needed, Ground	EC	NA	.5 lb (AE) A	UC	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, GP1
Low volume spray (concentrate), When needed, Aircraft	EC	NA	.5 lb (AE) A		*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, CSA(10), GP1

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year Dose cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
INDUSTRIAL AREAS (OUTDOOR) (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)							
	EC	NA		UC	* NS NS	NS NS NS	0.5 d				C92, CAL, GP1
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS				Use Group: TERRESTRIAL NON-FOOD CROP							
Broadcast, When needed, Ground	EC	NA	.5 lb (AE) A	UC	* NS NS	NS NS NS	0.5 d				C92, CAL, GP1
Low volume spray (concentrate), When needed, Aircraft	EC	NA	.5 lb (AE) A		* NS NS	NS NS NS	0.5 d				C92, CAL, CSA(10), GP1
	EC	NA		UC	* NS NS	NS NS NS	0.5 d				C92, CAL, GP1
Spray, Seedling stage, Aircraft	SC/L	NA		UC	* NS NS	NS NS NS	0.5 d		CA		C92, CAL, CSA(10), GK3
Spray, Seedling stage, Ground	SC/L	NA		UC	* NS NS	NS NS NS	0.5 d		CA		C92, CAL, GK3
ORNAMENTAL HERBACEOUS PLANTS				Use Group: TERRESTRIAL NON-FOOD CROP							
Broadcast, Dormant, Ground	EC	NA	.375 lb (AE) A		* 3 NS	NS NS NS	1 d	CA			C46
Directed spray, Cutting, Sprayer	EC	NA	.375 lb (AE) A		* 3 NS	NS NS NS	1 d	CA			C46
Directed spray, Established plantings, Sprayer	EC	NA	.375 lb (AE) A		* 3 NS	NS NS NS	1 d	CA			C46
Ground spray, Seedling stage, Ground	EC	NA	.25 lb (AE) A		* 2 NS	.5 lb (AE) NS NS	NS	MI			
Low volume spray (concentrate), Dormant, Aircraft	EC	NA	.375 lb (AE) A		* 3 NS	NS NS NS	1 d	CA			C46
ORNAMENTAL LAWNS AND TURF				Use Group: TERRESTRIAL NON-FOOD CROP							
Broadcast, Established plantings, Ground	EC	NA		UC	* NS NS	NS NS NS	0.5 d				C92, CAL

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
ORNAMENTAL LAWNS AND TURF (con't)			Use Group: TERRESTRIAL NON-FOOD CROP (con't)										
	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GK3
Broadcast, Preemergence, Ground	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL
	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GK3
Low volume spray (concentrate), Established plantings, Aircraft	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10)
	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10), GK3
Low volume spray (concentrate), Preemergence, Aircraft	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10)
	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10), GK3
Spray, Established plantings, Aircraft	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		CA	C92, CAL, CSA(10), GK3
Spray, Established plantings, Ground	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		CA	C92, CAL, GK3
Spray, Seedling stage, Aircraft	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		CA	C92, CAL, CSA(10), GK3
Spray, Seedling stage, Ground	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		CA	C92, CAL, GK3
ORNAMENTAL SOD FARM (TURF)			Use Group: TERRESTRIAL NON-FOOD CROP										
Broadcast, Established plantings, Ground	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G95
	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GK3
Broadcast, Preemergence, Ground	EC	NA	UC	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G95
	EC	NA	.5 lb (AE) A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GK3

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
ORNAMENTAL SOD FARM (TURF) (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)									
Low volume spray (concentrate), Established plantings, Aircraft	EC	NA		UC	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, CSA(10), G95
	EC	NA	.5 lb (AE)	A	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, CSA(10), GK3
Low volume spray (concentrate), Preemergence, Aircraft	EC	NA		UC	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, CSA(10), G95
	EC	NA	.5 lb (AE)	A	*	NS	NS	NS	NS	NS	0.5 d		C92, CAL, CSA(10), GK3
Spray, Established plantings, Aircraft	SC/L	NA		UC	*	NS	NS	NS	NS	NS	0.5 d	CA	C92, CAL, CSA(10), GK3
Spray, Established plantings, Ground	SC/L	NA		UC	*	NS	NS	NS	NS	NS	0.5 d	CA	C92, CAL, GK3
Spray, Seedling stage, Aircraft	SC/L	NA		UC	*	NS	NS	NS	NS	NS	0.5 d	CA	C92, CAL, CSA(10), GK3
Spray, Seedling stage, Ground	SC/L	NA		UC	*	NS	NS	NS	NS	NS	0.5 d	CA	C92, CAL, GK3

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

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LEGEND
444444

Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise) : Minimum dose for a single application to a single site. System calculated. Antimicrobial claims only.
Max. Appl. Rate (AI unless noted otherwise) : Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose : Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate : Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A] : Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days) : Minimum Interval between Applications (days)
Re-Entry Intv. : Reentry Intervals
PRD Report Date : LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

* : Non-specific
C : Coarse
M : Medium
F : Fine
O : Others

FORMULATION CODES

EC : EMULSIFIABLE CONCENTRATE
FM/L : FORM NOT IDENTIFIED/LIQUID
SC/L : SOLUBLE CONCENTRATE/LIQUID
WP : WETTABLE POWDER

ABBREVIATIONS

AN : As Needed
NA : Not Applicable
NS : Not Specified (on label)
UC : Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE

DCNC : Dosage Can Not be Calculated
No Calc : No Calculation can be made
W : PPM calculated by weight
V : PPM Calculated by volume
U : Unknown whether PPM is given by weight or by volume

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 035302 [Bromoxynil octanoate]

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APPLICATION RATE (CONT.)

cwt : Hundred Weight
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES

C13 : Groundwater restriction.
C46 : Do not apply through any type of irrigation system.
C48 : Conservation Reserve Acres.
C92 : For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.
CAC : Keep out of lakes, streams, and ponds.
CAL : Do not contaminate water, food or feed.
CCB : Rotational/plant back crop restriction.
CSA : Do not apply when wind velocity is _____ mph or greater.
CWE : This product is highly toxic to birds, fish, and other wildlife. Birds, especially waterfowl, feeding or drinking on treated areas may be killed.
CWH : Do not contaminate water by cleaning of equipment or disposal of equipment wash waters.
CWL : Do not contaminate water, food, or feed by storage or disposal.
G01 : __ day(s) pregrazing interval.
G83 : __ day(s) prefeeding interval.
G95 : Do not feed to livestock.
G96 : Do not graze livestock in treated areas or cut treated crops for feed.
GC1 : Do not graze treated areas.
GK3 : Do not feed forage to livestock or allow livestock to graze in treated areas.
GN5 : Do not graze treated fields for 30 days following treatment.
GN6 : Do not cut crop for feed or graze within 30 days after application.
GO3 : Do not cut green crop for feed or forage purposes.
GP1 : Do not graze or feed treated crop to livestock.
H01 : __ day(s) preharvest interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES

011 : West of the Mississippi River
012 : East of the Mississippi River
CA : California
CO : Colorado
MI : Michigan
MT : Montana
OR : Oregon
WA : Washington
WI : Wisconsin
WY : Wyoming

REENTRY INTERVAL ABBREVIATIONS

d : day(s)
h : hour(s)

UNIT DESCRIPTIONS

A : acre
lb : pound

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 128920 [3,5-Dibromo-4-hydroxyphenyl cyanide heptanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year Dose cycle	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES												
ALFALFA			Use Group: TERRESTRIAL FEED CROP									
Broadcast, Seedling stage, Ground	EC	NA	.2776 lb A	*	NS NS	.3701 lb	NS	NS	0.5 d			C92, CAL, G01(60), G83(60)
Chemigation, Seedling stage, Center pivot irrigation	EC	NA	.3701 lb A	*	NS NS	.3701 lb	NS	NS	0.5 d			C92, CAL, G01(60), G83(60)
Chemigation, Seedling stage, Hand move irrigation	EC	NA	.3701 lb A	*	NS NS	.3701 lb	NS	NS	0.5 d			C92, CAL, G01(60), G83(60)
Chemigation, Seedling stage, Moving wheel irrigation	EC	NA	.3701 lb A	*	NS NS	.3701 lb	NS	NS	0.5 d			C92, CAL, G01(60), G83(60)
Chemigation, Seedling stage, Solid set irrigation	EC	NA	.3701 lb A	*	NS NS	.3701 lb	NS	NS	0.5 d			C92, CAL, G01(60), G83(60)
Low volume spray (concentrate), Seedling stage, Aircraft	EC	NA	.2776 lb A	*	NS NS	.3701 lb	NS	NS	0.5 d			C92, CAL, CSA(10), G01(60), G83(60)
Spray, Seedling stage, Aircraft	SC/L	NA	UC	*	NS NS	UC	NS	NS	0.5 d	CA		C92, CAL, CSA(10), G01(60), G83(60)
Spray, Seedling stage, Ground	SC/L	NA	UC	*	NS NS	UC	NS	NS	0.5 d	CA		C92, CAL, G01(60), G83(60)
BARLEY			Use Group: TERRESTRIAL FOOD+FEED CROP									
Broadcast, Postemergence, Ground	EC	NA	.3701 lb A	*	NS NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Center pivot irrigation	EC	NA	.3701 lb A	*	NS NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Hand move irrigation	EC	NA	.3701 lb A	*	NS NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
	SC/L	NA	.3523 lb A	*	NS NS	NS	NS	NS	0.5 d			C92, CAL, GC1

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 128920 [3,5-Dibromo-4-hydroxyphenyl cyanide heptanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year Max. Dose /crop cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
BARLEY (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)								
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	.3701 lb A	*	NS	NS	NS	NS	0.5 d		C92, CAL, G01(30)
Chemigation, Postemergence, Solid set irrigation	EC	NA	.3701 lb A	*	NS	NS	NS	NS	0.5 d		C92, CAL, G01(30)
Chemigation, Postemergence, Sprinkler irrigation	SC/L	NA	.3523 lb A	*	NS	NS	NS	NS	0.5 d		C92, CAL, CSA(10), GC1
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.3701 lb A	*	NS	NS	NS	NS	0.5 d		C92, CAL, G01(30)
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	NS	NS	UC	NS	0.5 d	CA	C92, CAL, CSA(10), G01(30)
	SC/L	NA	.3523 lb A	*	NS	NS	NS	NS	0.5 d		C92, CAL, CSA(10), GC1
Spray, Postemergence, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	0.5 d	CA	C92, CAL, G01(30)
	SC/L	NA	.3523 lb A	*	NS	NS	NS	NS	0.5 d		C92, CAL, GC1
CORN, FIELD			Use Group: TERRESTRIAL FOOD+FEED CROP								
Broadcast, Postemergence, Ground	EC	NA	.5552 lb A	*	2	NS	.5552 lb	NS	7 0.5 d		C92, CAL, G01(30), G83(30)
Broadcast, Preemergence, Ground	EC	NA	.2776 lb A	*	NS	NS	.5552 lb	NS	NS 0.5 d		C92, CAL, G01(30), G83(30)
Broadcast, Preplant, Ground	EC	NA	.2776 lb A	*	NS	NS	.5552 lb	NS	NS 0.5 d		C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Center pivot irrigation	EC	NA	.3701 lb A	*	NS	NS	.5552 lb	NS	NS 0.5 d		C92, CAL, G01(30), G83(30)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 128920 [3,5-Dibromo-4-hydroxyphenyl cyanide heptanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
CORN, FIELD (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)										
Chemigation, Postemergence, Hand move irrigation	EC	NA	.3701 lb A	*	NS	NS	.5552 lb	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	.3701 lb A	*	NS	NS	.5552 lb	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Solid set irrigation	EC	NA	.3701 lb A	*	NS	NS	.5552 lb	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.5552 lb A	*	2	NS	.5552 lb	NS	7	0.5 d			C92, CAL, G01(30), G83(30)
Low volume spray (concentrate), Preemergence, Aircraft	EC	NA	.2776 lb A	*	NS	NS	.5552 lb	NS	NS	0.5 d			C92, CAL, CSA(10), G01(30), G83(30)
Low volume spray (concentrate), Preplant, Aircraft	EC	NA	.2776 lb A	*	NS	NS	.5552 lb	NS	NS	0.5 d			C92, CAL, CSA(10), G01(30), G83(30)
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	2	NS	UC	NS	7	0.5 d	CA		C92, CAL, CSA(10), GN6
Spray, Postemergence, Ground	SC/L	NA	UC	*	2	NS	UC	NS	7	0.5 d	CA		C92, CAL, GN6
Spray, Postemergence, Sprayer	WP	NA	UC .01763 gal A	* *	NS	NS	NS	NS	NS	12 h			C46, C92, CCB, CWE, CWH, CWL
Spray, Preemergence, Aircraft	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, CSA(10), GN6
Spray, Preemergence, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, GN6
Spray, Preemergence, Sprayer	WP	NA	UC .02644 gal A	* *	NS	NS	NS	NS	NS	12 h			C46, C92, CCB, CWE, CWH, CWL
CORN, POP			Use Group: TERRESTRIAL FOOD+FEED CROP										

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 128920 [3,5-Dibromo-4-hydroxyphenyl cyanide heptanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
CORN, POP (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)								
Broadcast, Postemergence, Ground	EC	NA	.5552 lb A	*	2 NS	.5552 lb	NS	7	0.5 d		C92, CAL, G01(30), G83(30)
Broadcast, Preemergence, Ground	EC	NA	.2776 lb A	*	NS NS	.5552 lb	NS	NS	0.5 d		C92, CAL, G01(30), G83(30)
Broadcast, Preplant, Ground	EC	NA	.2776 lb A	*	NS NS	.5552 lb	NS	NS	0.5 d		C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Center pivot irrigation	EC	NA	.3701 lb A	*	NS NS	.5552 lb	NS	NS	0.5 d		C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Hand move irrigation	EC	NA	.3701 lb A	*	NS NS	.5552 lb	NS	NS	0.5 d		C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	.3701 lb A	*	NS NS	.5552 lb	NS	NS	0.5 d		C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Solid set irrigation	EC	NA	.3701 lb A	*	NS NS	.5552 lb	NS	NS	0.5 d		C92, CAL, G01(30), G83(30)
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.5552 lb A	*	2 NS	.5552 lb	NS	7	0.5 d		C92, CAL, G01(30), G83(30)
Low volume spray (concentrate), Preemergence, Aircraft	EC	NA	.2776 lb A	*	NS NS	.5552 lb	NS	NS	0.5 d		C92, CAL, CSA(10), G01(30), G83(30)
Low volume spray (concentrate), Preplant, Aircraft	EC	NA	.2776 lb A	*	NS NS	.5552 lb	NS	NS	0.5 d		C92, CAL, CSA(10), G01(30), G83(30)
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	2 NS	UC	NS	7	0.5 d	CA	C92, CAL, CSA(10), GN6
Spray, Postemergence, Ground	SC/L	NA	UC	*	2 NS	UC	NS	7	0.5 d	CA	C92, CAL, GN6
Spray, Postemergence, Sprayer	WP	NA	.01763 gal A	*	NS NS	NS	NS	NS	12 h		C46, C92, CCB, CWE, CWH, CWL

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 128920 [3,5-Dibromo-4-hydroxyphenyl cyanide heptanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
CORN, POP (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)									
Spray, Preemergence, Aircraft	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, CSA(10), GN6
Spray, Preemergence, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, GN6
Spray, Preemergence, Sprayer	WP	NA	.02644 gal A	*	NS	NS	NS	NS	NS	12 h			C46, C92, CCB, CWE, CWH, CWL
CORN, SWEET				Use Group: TERRESTRIAL FOOD+FEED CROP									
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, CSA(10), GN6
Spray, Postemergence, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, GN6
Spray, Preemergence, Aircraft	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, CSA(10), GN6
Spray, Preemergence, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, GN6
COTTON (UNSPECIFIED)				Use Group: TERRESTRIAL FOOD+FEED CROP									
Band treatment, Postemergence, Ground	EC	NA	.3701 lb A	*	3	NS	1.11 lb	NS	NS	0.5 d			C92, CAL, GC1, GO3, H01(60)
Band treatment, Preemergence, Ground	EC	NA	.3701 lb A	*	NS	NS	1.11 lb	NS	NS	0.5 d			C92, CAL, GC1, GO3, H01(60)
Band treatment, Preplant, Ground	EC	NA	.3701 lb A	*	NS	NS	1.11 lb	NS	NS	0.5 d			C92, CAL, GC1, GO3, H01(60)
Broadcast, Postemergence, Ground	EC	NA	.3701 lb A	*	3	NS	1.11 lb	NS	NS	0.5 d			C92, CAL, GC1, GO3, H01(60)
Broadcast, Preemergence, Ground	EC	NA	.3701 lb A	*	NS	NS	1.11 lb	NS	NS	0.5 d			C92, CAL, GC1, GO3, H01(60)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 128920 [3,5-Dibromo-4-hydroxyphenyl cyanide heptanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year Dose cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
COTTON (UNSPECIFIED) (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)								
Broadcast, Preplant, Ground	EC	NA	.3701 lb A	*	NS NS	1.11 lb	NS	0.5 d			C92, CAL, GC1, GO3, H01(60)
FLAX			Use Group: TERRESTRIAL FOOD+FEED CROP								
Broadcast, Postemergence, Ground	EC	NA	.1851 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.1851 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	NS NS	NS	NS	0.5 d	CA		C92, CAL, CSA(10)
Spray, Postemergence, Ground	SC/L	NA	UC	*	NS NS	NS	NS	0.5 d	CA		C92, CAL
GARLIC			Use Group: TERRESTRIAL FOOD CROP								
Broadcast, Postemergence, Ground	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, H01(112)
Chemigation, Postemergence, Center pivot irrigation	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, H01(112)
Chemigation, Postemergence, Hand move irrigation	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, H01(112)
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, H01(112)
Chemigation, Postemergence, Solid set irrigation	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, H01(112)
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, H01(112)
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	NS NS	NS	NS	0.5 d	CA		C92, CAL, H01(112)
Spray, Postemergence, Ground	SC/L	NA	UC	*	NS NS	NS	NS	0.5 d	CA		C92, CAL, H01(112)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 128920 [3,5-Dibromo-4-hydroxyphenyl cyanide heptanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop	/year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
OATS			Use Group: TERRESTRIAL FOOD+FEED CROP										
Broadcast, Postemergence, Ground	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d	OR, WA, CO, WY, MT		C92, CAL, G01(30)
Chemigation, Postemergence, Center pivot irrigation	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d	OR, WA, CO, WY, MT		C92, CAL, G01(30)
Chemigation, Postemergence, Hand move irrigation	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d	OR, WA, CO, WY, MT		C92, CAL, G01(30)
	SC/L	NA	.3523 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d	OR, WA, CO, WY, MT		C92, CAL, G01(30)
Chemigation, Postemergence, Solid set irrigation	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d	OR, WA, CO, WY, MT		C92, CAL, G01(30)
Chemigation, Postemergence, Sprinkler irrigation	SC/L	NA	.3523 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d	OR, WA, CO, WY, MT		C92, CAL, G01(30)
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d		CA	C92, CAL, CSA(10), G01(30)
	SC/L	NA	.3523 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10), G01(30)
Spray, Postemergence, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d		CA	C92, CAL, G01(30)
	SC/L	NA	.3523 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
ONION			Use Group: TERRESTRIAL FOOD CROP										
Broadcast, Postemergence, Ground	EC	NA	.2776 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 128920 [3,5-Dibromo-4-hydroxyphenyl cyanide heptanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year Dose cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
ONION (con't)				Use Group: TERRESTRIAL FOOD CROP (con't)							
Broadcast, Preemergence, Ground	EC	NA	.2776 lb A	*	NS NS	NS NS	NS	0.5 d			C92, CAL
Broadcast, Preplant, Ground	EC	NA	.2776 lb A	*	NS NS	NS NS	NS	0.5 d			C92, CAL
Chemigation, Postemergence, Center pivot irrigation	EC	NA	.2776 lb A	*	NS NS	NS NS	NS	0.5 d			C92, CAL
Chemigation, Postemergence, Hand move irrigation	EC	NA	.2776 lb A	*	NS NS	NS NS	NS	0.5 d			C92, CAL
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	.2776 lb A	*	NS NS	NS NS	NS	0.5 d			C92, CAL
Chemigation, Postemergence, Solid set irrigation	EC	NA	.2776 lb A	*	NS NS	NS NS	NS	0.5 d			C92, CAL
Spray, Postemergence, Ground	SC/L	NA	UC	*	NS NS	NS NS	NS	0.5 d	CA		C92, CAL
Spray, Preemergence, Aircraft	SC/L	NA	UC	*	NS NS	NS NS	NS	0.5 d	CA, 011		C92, CAL, CSA(10)
Spray, Preemergence, Ground	SC/L	NA	UC	*	NS NS	NS NS	NS	0.5 d	CA, 011		C92, CAL
PEPPERMINT				Use Group: TERRESTRIAL FOOD+FEED CROP							
Broadcast, Dormant, Ground	EC	NA	.2776 lb A	*	NS NS	2.221 lb NS	NS	0.5 d			C92, CAL, H01(70)
Broadcast, Established plantings, Ground	EC	NA	.2776 lb A	*	NS NS	2.221 lb NS	NS	0.5 d			C92, CAL, H01(70)
Spray, Dormant, Ground	SC/L	NA	UC	*	NS NS	UC NS	NS	0.5 d	CA		C92, CAL, H01(70)
Spray, Established plantings, Ground	SC/L	NA	UC	*	NS NS	UC NS	NS	0.5 d	CA		C92, CAL, H01(70)
RYE				Use Group: TERRESTRIAL FOOD+FEED CROP							
Broadcast, Postemergence, Ground	EC	NA	.3701 lb A	*	NS NS	NS NS	NS	0.5 d			C92, CAL, G01(30)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 128920 [3,5-Dibromo-4-hydroxyphenyl cyanide heptanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year Dose cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
RYE (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)								
Chemigation, Postemergence, Center pivot irrigation	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Hand move irrigation	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, G01(30)
	SC/L	NA	.3523 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Solid set irrigation	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Sprinkler irrigation	SC/L	NA	.3523 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, G01(30)
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, G01(30)
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	NS NS	UC	NS	0.5 d	CA		C92, CAL, CSA(10), G01(30)
	SC/L	NA	.3523 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, CSA(10), G01(30)
Spray, Postemergence, Ground	SC/L	NA	UC	*	NS NS	UC	NS	0.5 d	CA		C92, CAL, G01(30)
	SC/L	NA	.3523 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, G01(30)
SORGHUM			Use Group: TERRESTRIAL FEED CROP								
Broadcast, Postemergence, Ground	EC	NA	.5552 lb A	*	2 NS	.5552 lb	NS	7 0.5 d			C92, CAL, G01(30), G83(30)
Broadcast, Preemergence, Ground	EC	NA	.2776 lb A	*	NS NS	.5552 lb	NS	NS 0.5 d			C92, CAL, G01(30), G83(30)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 128920 [3,5-Dibromo-4-hydroxyphenyl cyanide heptanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	# Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
SORGHUM (con't)			Use Group: TERRESTRIAL FEED CROP (con't)										
Broadcast, Preplant, Ground	EC	NA	.2776 lb A	*	NS	NS	.5552 lb	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Center pivot irrigation	EC	NA	.3701 lb A	*	NS	NS	.5552 lb	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Hand move irrigation	EC	NA	.3701 lb A	*	NS	NS	.5552 lb	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	.3701 lb A	*	NS	NS	.5552 lb	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Solid set irrigation	EC	NA	.3701 lb A	*	NS	NS	.5552 lb	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.5552 lb A	*	2	NS	.5552 lb	NS	7	0.5 d			C92, CAL, G01(30), G83(30)
Low volume spray (concentrate), Preemergence, Aircraft	EC	NA	.2776 lb A	*	NS	NS	.5552 lb	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Low volume spray (concentrate), Preplant, Aircraft	EC	NA	.2776 lb A	*	NS	NS	.5552 lb	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	2	NS	UC	NS	7	0.5 d	CA		C92, CAL, CSA(10), GN6
Spray, Postemergence, Ground	SC/L	NA	UC	*	2	NS	UC	NS	7	0.5 d	CA		C92, CAL, GN6
Spray, Postemergence, Sprayer	WP	NA	.01763 gal A	*	NS	NS	NS	NS	NS	12 h			C46, C92, CCB, CWE, CWH, CWL
Spray, Preemergence, Aircraft	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, CSA(10), GN6
Spray, Preemergence, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, GN6

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 128920 [3,5-Dibromo-4-hydroxyphenyl cyanide heptanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
SORGHUM (con't)				Use Group: TERRESTRIAL FEED CROP (con't)									
Spray, Preemergence, Sprayer	WP	NA	.02644 gal A	*	NS	NS	NS	NS	NS	12 h			C46, C92, CCB, CWE, CWH, CWL
				Use Group: TERRESTRIAL FOOD+FEED CROP									
Broadcast, Postemergence, Ground	EC	NA	.5552 lb A	*	2	NS	.5552 lb	NS	7	0.5 d			C92, CAL, G01(30), G83(30)
Broadcast, Preemergence, Ground	EC	NA	.2776 lb A	*	NS	NS	.5552 lb	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Broadcast, Preplant, Ground	EC	NA	.2776 lb A	*	NS	NS	.5552 lb	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Center pivot irrigation	EC	NA	.3701 lb A	*	NS	NS	.5552 lb	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Hand move irrigation	EC	NA	.3701 lb A	*	NS	NS	.5552 lb	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	.3701 lb A	*	NS	NS	.5552 lb	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Chemigation, Postemergence, Solid set irrigation	EC	NA	.3701 lb A	*	NS	NS	.5552 lb	NS	NS	0.5 d			C92, CAL, G01(30), G83(30)
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.5552 lb A	*	2	NS	.5552 lb	NS	7	0.5 d			C92, CAL, G01(30), G83(30)
Low volume spray (concentrate), Preemergence, Aircraft	EC	NA	.2776 lb A	*	NS	NS	.5552 lb	NS	NS	0.5 d			C92, CAL, CSA(10), G01(30), G83(30)
Low volume spray (concentrate), Preplant, Aircraft	EC	NA	.2776 lb A	*	NS	NS	.5552 lb	NS	NS	0.5 d			C92, CAL, CSA(10), G01(30), G83(30)
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	2	NS	UC	NS	7	0.5 d		CA	C92, CAL, CSA(10), GN6

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 128920 [3,5-Dibromo-4-hydroxyphenyl cyanide heptanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
SORGHUM (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)									
Spray, Postemergence, Ground	SC/L	NA	UC	*	2	NS	UC	NS	7	0.5 d	CA		C92, CAL, GN6
Spray, Postemergence, Sprayer	WP	NA	.01763 gal A	*	NS	NS	NS	NS	NS	12 h			C46, C92, CCB, CWE, CWH, CWL
Spray, Preemergence, Aircraft	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, CSA(10), GN6
Spray, Preemergence, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, GN6
Spray, Preemergence, Sprayer	WP	NA	.02644 gal A	*	NS	NS	NS	NS	NS	12 h			C46, C92, CCB, CWE, CWH, CWL
SPEARMINT				Use Group: TERRESTRIAL FOOD+FEED CROP									
Broadcast, Dormant, Ground	EC	NA	.2776 lb A	*	NS	NS	2.221 lb	NS	NS	0.5 d			C92, CAL, H01(70)
Broadcast, Established plantings, Ground	EC	NA	.2776 lb A	*	NS	NS	2.221 lb	NS	NS	0.5 d			C92, CAL, H01(70)
Spray, Dormant, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, H01(70)
Spray, Established plantings, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, H01(70)
SUDANGRASS				Use Group: TERRESTRIAL FEED CROP									
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d	CA		C92, CAL, CSA(10)
Spray, Postemergence, Ground	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d	CA		C92, CAL
TRITICALE				Use Group: TERRESTRIAL FOOD+FEED CROP									
Broadcast, Postemergence, Ground	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Center pivot irrigation	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 128920 [3,5-Dibromo-4-hydroxyphenyl cyanide heptanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year Dose cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
TRITICALE (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)								
Chemigation, Postemergence, Hand move irrigation	EC	NA	.3701 lb A	* NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	.3701 lb A	* NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Solid set irrigation	EC	NA	.3701 lb A	* NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.3701 lb A	* NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Spray, Postemergence, Aircraft	SC/L	NA	UC	* NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, CSA(10), G01(30)
Spray, Postemergence, Ground	SC/L	NA	UC	* NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, G01(30)
WHEAT				Use Group: TERRESTRIAL FOOD+FEED CROP								
Broadcast, Postemergence, Ground	EC	NA	.3701 lb A	* NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Center pivot irrigation	EC	NA	.3701 lb A	* NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Hand move irrigation	EC	NA	.3701 lb A	* NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
	SC/L	NA	.3523 lb A	* NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Moving wheel irrigation	EC	NA	.3701 lb A	* NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Solid set irrigation	EC	NA	.3701 lb A	* NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Chemigation, Postemergence, Sprinkler irrigation	SC/L	NA	.3523 lb A	* NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 128920 [3,5-Dibromo-4-hydroxyphenyl cyanide heptanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Dose	Tex. @ Max. Rate	# Apps /crop cycle	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
WHEAT (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)										
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
Spray, Postemergence, Aircraft	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, CSA(10), G01(30)
	SC/L	NA	.3523 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10), G01(30)
Spray, Postemergence, Ground	SC/L	NA	UC	*	NS	NS	UC	NS	NS	0.5 d	CA		C92, CAL, G01(30)
	SC/L	NA	.3523 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, G01(30)
NON-FOOD/NON-FEED													
AGRICULTURAL FALLOW/IDLELAND			Use Group: TERRESTRIAL NON-FOOD CROP										
Broadcast, Postemergence, Ground	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GK3
Low volume spray (concentrate), Postemergence, Aircraft	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GK3
Spray, When needed, Aircraft	SC/L	NA	.3523 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10), GK3
	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d	CA		C92, CAL, CSA(10), GK3
Spray, When needed, Ground	SC/L	NA	.3523 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GK3
	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d	CA		C92, CAL, GK3
COMMERCIAL/INDUSTRIAL LAWNS			Use Group: TERRESTRIAL NON-FOOD CROP										
Broadcast, Established plantings, Ground	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 128920 [3,5-Dibromo-4-hydroxyphenyl cyanide heptanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year Max. Dose /crop cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
COMMERCIAL/INDUSTRIAL LAWNS (con't)			Use Group: TERRESTRIAL NON-FOOD CROP (con't)								
Broadcast, Preemergence, Ground	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL
Low volume spray (concentrate), Established plantings, Aircraft	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, CSA(10)
Low volume spray (concentrate), Preemergence, Aircraft	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, CSA(10)
Spray, Seedling stage, Aircraft	SC/L	NA	UC	*	NS NS	NS	NS	0.5 d	CA		C92, CAL, CSA(10)
Spray, Seedling stage, Ground	SC/L	NA	UC	*	NS NS	NS	NS	0.5 d	CA		C92, CAL
GOLF COURSE TURF			Use Group: TERRESTRIAL NON-FOOD CROP								
Broadcast, Established plantings, Ground	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL
Broadcast, Preemergence, Ground	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL
Low volume spray (concentrate), Established plantings, Aircraft	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, CSA(10)
Low volume spray (concentrate), Preemergence, Aircraft	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, CSA(10)
GRASSES GROWN FOR SEED			Use Group: TERRESTRIAL NON-FOOD CROP								
Broadcast, Established plantings, Ground	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, G95
Broadcast, Preemergence, Ground	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, G95
Low volume spray (concentrate), Established plantings, Aircraft	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, CSA(10), G95
Low volume spray (concentrate), Preemergence, Aircraft	EC	NA	.3701 lb A	*	NS NS	NS	NS	0.5 d			C92, CAL, CSA(10), G95

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 128920 [3,5-Dibromo-4-hydroxyphenyl cyanide heptanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
GRASSES GROWN FOR SEED (con't)			Use Group: TERRESTRIAL NON-FOOD CROP (con't)										
Spray, Established plantings, Aircraft	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d	CA		C92, CAL, CSA(10), GK3
Spray, Established plantings, Ground	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d	CA		C92, CAL, GK3
Spray, Seedling stage, Aircraft	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d	CA		C92, CAL, CSA(10), GK3
Spray, Seedling stage, Ground	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d	CA		C92, CAL, GK3
INDUSTRIAL AREAS (OUTDOOR)			Use Group: TERRESTRIAL NON-FOOD CROP										
Broadcast, When needed, Ground	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GP1
Low volume spray (concentrate), When needed, Aircraft	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GP1
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS			Use Group: TERRESTRIAL NON-FOOD CROP										
Broadcast, When needed, Ground	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GP1
Low volume spray (concentrate), When needed, Aircraft	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, GP1
Spray, Seedling stage, Aircraft	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d	CA		C92, CAL, CSA(10), GK3
Spray, Seedling stage, Ground	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d	CA		C92, CAL, GK3
ORNAMENTAL LAWNS AND TURF			Use Group: TERRESTRIAL NON-FOOD CROP										
Broadcast, Established plantings, Ground	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL
Broadcast, Preemergence, Ground	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL
Low volume spray (concentrate), Established plantings, Aircraft	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d			C92, CAL, CSA(10)

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 128920 [3,5-Dibromo-4-hydroxyphenyl cyanide heptanoate]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Dose	Tex.	# Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION														
NON-FOOD/NON-FEED (con't)														
ORNAMENTAL LAWNS AND TURF (con't)			Use Group: TERRESTRIAL NON-FOOD CROP (con't)											
Low volume spray (concentrate), Preemergence, Aircraft	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d				C92, CAL, CSA(10)
Spray, Established plantings, Aircraft	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		CA		C92, CAL, CSA(10), GK3
Spray, Established plantings, Ground	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		CA		C92, CAL, GK3
Spray, Seedling stage, Aircraft	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		CA		C92, CAL, CSA(10), GK3
Spray, Seedling stage, Ground	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		CA		C92, CAL, GK3
ORNAMENTAL SOD FARM (TURF)			Use Group: TERRESTRIAL NON-FOOD CROP											
Broadcast, Established plantings, Ground	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d				C92, CAL, G95
Broadcast, Preemergence, Ground	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d				C92, CAL, G95
Low volume spray (concentrate), Established plantings, Aircraft	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d				C92, CAL, CSA(10), G95
Low volume spray (concentrate), Preemergence, Aircraft	EC	NA	.3701 lb A	*	NS	NS	NS	NS	NS	0.5 d				C92, CAL, CSA(10), G95
Spray, Established plantings, Aircraft	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		CA		C92, CAL, CSA(10), GK3
Spray, Established plantings, Ground	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		CA		C92, CAL, GK3
Spray, Seedling stage, Aircraft	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		CA		C92, CAL, CSA(10), GK3
Spray, Seedling stage, Ground	SC/L	NA	UC	*	NS	NS	NS	NS	NS	0.5 d		CA		C92, CAL, GK3

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 128920 [3,5-Dibromo-4-hydroxyphenyl cyanide heptanoate]
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LEGEND
444444

Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	: Minimum dose for a single application to a single site. System calculated. Antimicrobial claims only.
Max. Appl. Rate (AI unless noted otherwise)	: Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose	: Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate	: Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A]	: Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days)	: Minimum Interval between Applications (days)
Re-Entry Intv.	: Reentry Intervals
PRD Report Date	: LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

*	: Non-specific
C	: Coarse
M	: Medium
F	: Fine
O	: Others

FORMULATION CODES

EC	: EMULSIFIABLE CONCENTRATE
SC/L	: SOLUBLE CONCENTRATE/LIQUID
WP	: WETTABLE POWDER

ABBREVIATIONS

AN	: As Needed
NA	: Not Applicable
NS	: Not Specified (on label)
UC	: Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE

DCNC	: Dosage Can Not be Calculated
No Calc	: No Calculation can be made
W	: PPM calculated by weight
V	: PPM Calculated by volume
U	: Unknown whether PPM is given by weight or by volume

APPENDIX A REPORT

Case 2070 [Bromoxynil, and esters] Chemical 128920 [3,5-Dibromo-4-hydroxyphenyl cyanide heptanoate]

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APPLICATION RATE (CONT.)

cwt : Hundred Weight
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES

C46 : Do not apply through any type of irrigation system.
C92 : For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.
CAL : Do not contaminate water, food or feed.
CCB : Rotational/plant back crop restriction.
CSA : Do not apply when wind velocity is _____ mph or greater.
CWE : This product is highly toxic to birds, fish, and other wildlife. Birds, especially waterfowl, feeding or drinking on treated areas may be killed.
CWH : Do not contaminate water by cleaning of equipment or disposal of equipment wash waters.
CWL : Do not contaminate water, food, or feed by storage or disposal.
G01 : __ day(s) pregrazing interval.
G83 : __ day(s) prefeeding interval.
G95 : Do not feed to livestock.
GC1 : Do not graze treated areas.
GK3 : Do not feed forage to livestock or allow livestock to graze in treated areas.
GN6 : Do not cut crop for feed or graze within 30 days after application.
GO3 : Do not cut green crop for feed or forage purposes.
GP1 : Do not graze or feed treated crop to livestock.
H01 : __ day(s) preharvest interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES

011 : West of the Mississippi River
CA : California
CO : Colorado
MT : Montana
OR : Oregon
WA : Washington
WY : Wyoming

REENTRY INTERVAL ABBREVIATIONS

d : day(s)
h : hour(s)

UNIT DESCRIPTIONS

A : acre
gal : gallon
lb : pound

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case BROMOXYNIL covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to BROMOXYNIL in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Bromoxynil

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	ALL	41943901
61-2A	Start. Mat. & Mnfg. Process	ALL	41943901
61-2B	Formation of Impurities	ALL	41943901
62-1	Preliminary Analysis	ALL	41943901
62-2	Certification of Limits	ALL	41943901
62-3	Analytical Method	ALL	41943901
63-2	Color	ALL	41943901
63-3	Physical State	ALL	41943901
63-4	Odor	ALL	41943901
63-5	Melting Point	ALL	41943901
63-7	Density	ALL	42333601, 41943901
63-8	Solubility	ALL	41943901, 42087401
63-9	Vapor Pressure	ALL	41943901, 42130101
63-10	Dissociation Constant	ALL	42066401
63-11	Octanol/Water Partition	ALL	41943901, 42333601
63-12	pH	ALL	41943901, 42333601
63-13	Stability	ALL	41943901
63-14	Oxidizing/Reducing Action	ALL	42333601
63-17	Storage Stability	ALL	42333601
63-18	Viscosity	All	41943901
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	A,B,C,K, L,M	00124758, 00124112
81-2	Acute Dermal Toxicity - Rabbit/Rat	A,B,C,K, L,M	00124758, 00124112

Data Supporting Guideline Requirements for the Reregistration of Bromoxynil

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
81-3	Acute Inhalation Toxicity - Rat	A,B,C,K, L,M	43014701, 42167101
81-4	Primary Eye Irritation - Rabbit	A,B,C,K, L,M	00124758, 00124112
81-5	Primary Dermal Irritation - Rabbit	A,B,C,K, L,M	00124758, 00124112
81-6	Dermal Sensitization - Guinea Pig	A,B,C,K, L,M	42718701, 41879801
81-8	Acute Neurotoxicity - Rat	A,B,C,K, L,M	Reserved
82-1A	90-Day Feeding - Rat	A,B,C,K, L,M	41469101, 42411901
82-1A	90-Day Feeding - Mouse	A,B,C,K, L,M	42553401
82-1B	90-Day Feeding - Non-rodent	A,B,C,K, L,M	43166701, 42869701, 43700201, 00061179
82-3	90-day Dermal - Rabbit	A,B,C,K, L,M	42272301, 42346201
82-7	90-Day Neurotoxicity - Rat	A,B,C,K, L,M	Reserved
83-1A	Chronic Feeding Toxicity- Rat	A,B,C,K, L,M	00096521, 40612501, 41374801
83-1B	Chronic Feeding Toxicity - Non-rodent	A,B,C,K, L,M	40780301, 41304701
83-2A	Oncogenicity - Rat	A,B,D,H,L	00096521, 40612501, 41374801
83-2B	Oncogenicity - Mouse	A,B,D,H,L	00068077, 43245501, 43311701
83-3A	Developmental Toxicity - Rat	A,B,C,K, L,M	40466802, 00116558, 40881201, 40883601, 41163301
83-3B	Developmental Toxicity - Rabbit	A,B,D,H,L	00138149, 00142779, 40935101, 41307801, 41471901, 42183901

Data Supporting Guideline Requirements for the Reregistration of Bromoxynil

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
83-4	2-Generation Reproduction - Rat	A,B,C,K, L,M	41149301, 00064815, 41667401
84-2A	Gene Mutation (Ames Test)	A,B,C,K, L,M	41995701, 43022701, 00115649, 41995702
84-2B	Structural Chromosomal Aberration	A,B,C,K, L,M	00115651, 00124803, 42092301, 41930802
84-4	Other Genotoxic Effects	A,B,C,K, L,M	00115646, 001156547, 00115648, 00115650, 42078901
85-1	General Metabolism	A,B,D,H,L	43191401, 00154756, 00154757, 42901001,
85-2	Dermal Penetration	ALL	40854602, 40854603
85-7	Immunotoxicity	A,B,C,K, L,M	Reserved
ENVIRONMENTAL FATE			
161-1	Hydrolysis	A,B,C,K, L,M	41892901, 00130424
161-2	Photodegredation - Water	A,B,C,D E,F,G,J	42234301, 41920401
161-3	Photoegradation - Soil	A,B,C,J	41920402
162-1	Aerobic Soil Metabolism	A,B,C,H I,J,K	42234302, 41897701, 00142958
162-3	Anaerobic Aquatic Metabolism	A,B,C,D E,F,G,J	42234303, 41892902
162-4	Aerobic Aquatic Metabolism	D,E,F,G J	42364901
163-1	Leach/adsorp/desorp	A,B,C,D E,F,G,H I,J,K	42271101, 43775001
164-1	Terrestrial Field Dissipation	A,B,C,K	41653701, 43071001
166-1	Small Scale Prospective - Groundwater	A,B,C,K	Reserved
166-2	Small Scale Retrospective - Groundwater	A,B,C,K	Reserved

Data Supporting Guideline Requirements for the Reregistration of Bromoxynil

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
ENVIRONMENTAL TOXICOLOGY			
71-1A	Acute Avian - Oral	A,B,C,D, E,F,J,K	248229, 258887, 43030001
71-2A/B	Acute Avian - Dietary, Quail/Duck	A,B,C,D, E,F,J,K	4303002, 248229, 258886, 258888, 247924
71-4A/B	Avain Repro - Quail/Duck	A,B,C,D, E,F,J,K	42004101, 42475801, 42004102
72-1A	Fish Toxicity - Bluegill	A,B,C,D, E,F,J,K	248229, 43059601,
72-1C	Fish Toxicity - Rainbow Trout	A,B,C,D, E,F,J,K	247924, 264229, 072254, 260441
72-2A	Invertebrate Toxicity	A,B,C,D, E,F,J,K	247924, 260441, 248229, 00138087
72-3A	Estuarine/Marine Toxicity - Fish	A,B,C,D, E,F,J,K	42250601
72-3C	Estuarine/Marine Toxicity - Shrimp	A,B,C,D, E,F,J,K	42244501, 43487601
72-4A	Early Life Stage - Fish	A,B,C,D, E,F,J,K	41928301, 4011103
72-4B	Early Life Stage - Invertebrate	A,B,C,D, E,F,J,K	41928302, 40111001
123-2	Seed Germ/Emergence - Vegatative Vigor	A,B,C,D, E,F,J,K	43633701, 4160601, 41606002, 41606004, 41606005; Data Gap
141-1	Honey Bee Acute Contact	A,B,C,D, E,F,J,K	00018842
172-4	Estuarine/Marine Organisms - Chronic	A,B,C,D, E,F,J,K	Data Gap

Data Supporting Guideline Requirements for the Reregistration of Bromoxynil

REQUIREMENT		USE PATTERN	CITATION(S)(MRID#)
RESIDUE CHEMISTRY			
860.1200	Directions for Use	All	
860.1300	Plant Metabolism	A,B,C,K, L,M	00115594, 00165547
860.1300	Livestock Metabolism	A,B,C,K, L,M	42346401, 42346402
860.1340	Residue Analytical Methods	A,B,C,K, L,M	00075671, 00084589
860.1360	Multiresidue Methods - Plants and Livestock	A,B,C,K, L,M	00139591
860.1380	Storage Stability	A,B,C,K, L,M	43108801
860.1480	Meat, Milk, Poultry and Eggs	A,B,C,K, L,M	43389001, 43307001
860.1500	Crop Field Trials	A,B,C,K, L,M	42950101, 42540601, 42757601, 42540602, 43648102, 42950102, 43648101, 43506901, 43108801
860.1900	Processed Food/Feed	A,B,C,K, L,M	42460502, 42571401, 42571401, 43648101, 42465401, 42950103

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

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a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient(s) identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient(s). Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. how you will comply with the requirements set forth in this Notice and its Attachments 1 through 4; or,

2. why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or,

3. why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 4).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-99).

This Notice is divided into six sections and five Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I	-	Why You Are Receiving This Notice
Section II	-	Data Required By This Notice
Section III	-	Compliance With Requirements Of This Notice
Section IV	-	Consequences Of Failure To Comply With This Notice
Section V	-	Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI	-	Inquiries And Responses To This Notice

The Attachments to this Notice are:

Attachment 1	-	Data Call-In Chemical Status Sheet
Attachment 2	-	Data Call-In Response Form (Insert A)
Attachment 3	-	Requirements Status And Registrant's Response Form (Insert B)
Attachment 4	-	List Of All Registrants Sent This Data Call-In Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredient(s).

SECTION II. DATA REQUIRED BY THIS NOTICE

A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Form (Insert B). Depending on the results of the studies required in this Notice, additional testing may be required.

B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form (Insert B), within the time frames provided.

C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice are: 1) voluntary cancellation, 2) delete use(s), (3) claim generic data exemption, (4) agree to satisfy the data requirements imposed by this Notice or (5) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form (Insert A) and the Requirements Status and Registrant's Response Form (Insert B). The Data Call-In Response Form (Insert A) must be submitted as part of every response to this Notice. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form (Insert A) and Requirements Status and Registrant's Response Form (Insert B) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient(s) that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form (Insert A), indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form (Insert A). If you choose this option, this is the only form that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Use Deletion - You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Insert B), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 on the Requirements Status and Registrant's Response Form (Insert B). You must also complete a Data Call-In Response Form (Insert A) by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support and Emergency Response Branch, Registration Division, (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, must bear an amended label.

3. Generic Data Exemption - Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient(s) if the active ingredient(s) in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient(s). EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

a. The active ingredient(s) in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient(s) and is purchased from a source not connected with you; and,

b. every registrant who is the ultimate source of the active ingredient(s) in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

c. you must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form (Insert A), and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form (Insert A). If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form (Insert B). Generic Data Exemption cannot be selected as an option for product specific data.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

4. Satisfying the Data Requirements of this Notice - There are various options available to satisfy the data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form (Insert B) and option 6b and 7 on the Data Call-In Response Form(Insert A). If you choose option 6b or 7, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

5. Request for Data Waivers. Data waivers are discussed in Section III-D of this Notice and are covered by options 8 and 9 on the Requirements Status and Registrant's Response Form (Insert B). If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

C. SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form (Insert A) that you agree to satisfy the data requirements (i.e. you select option 6b and/or 7), then you must select one of the six options on the Requirements Status and Registrant's Response Form (Insert A) related to data production for

each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form (Insert B). These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

1. I will generate and submit data within the specified time frame (Developing Data),

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing),

3. I have made offers to cost-share (Offers to Cost Share),

4. I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study),

5. I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study),

6. I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study).

Option 1, Developing Data

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form (Insert B) and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost-share or agreeing to share in the cost of developing that study. A 90-day progress report must be submitted for all studies. This 90-day progress report must include the date the study was or will be initiated and, for studies

to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form (Insert B) are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirement(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data --

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development --

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form (Insert A) and a Requirements Status and Registrant's Response Form (Insert B) committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study --

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(7) " *raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. *Raw data* may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(7), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such a study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study --

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies --

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of Certification with Respect to Citations of Data (in PR Notice 98-5) EPA Form 8570-34 .

D. REQUESTS FOR DATA WAIVERS

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are inapplicable and do not apply to your product.

1. Low Volume/Minor Use Waiver -- Option 8 on the Requirements Status and Registrant's Response Form (Insert B). Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision EPA considers as low volume pesticides only those active ingredient(s) whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient(s) is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient(s) are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient(s) elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

a. Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient(s). If applicable to the active ingredient(s), include foreign sales for those products that are not registered in this country but are applied

to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

b. Provide an estimate of the sales (pounds and dollars) of the active ingredient(s) for each major use site. Present the above information by year for each of the past five years.

c. Total direct production cost of product(s) containing the active ingredient(s) by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

d. Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient(s) by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient(s), such as costs of initial registration and any data development.

e. A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

f. A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

g. For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient(s), direct production costs of product(s) containing the active ingredient(s) (following the parameters in item c above), indirect production costs of product(s) containing the active ingredient(s) (following the parameters in item d above), and costs of data development pertaining to the active ingredient(s).

h. A description of the importance and unique benefits of the active ingredient(s) to users. Discuss the use patterns and the effectiveness of the active ingredient(s) relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient(s), providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient(s) in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s):

(1) documentation of the usefulness of the active ingredient(s) in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient(s), as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient(s) after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume minor use waiver will result in denial of the request for a waiver.

2. Request for Waiver of Data --Option 9 on the Requirements Status and Registrant's Response Form (Insert B). This option may be used if you believe that a particular data requirement should not apply because the corresponding use is no longer registered or the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You must also submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice do not apply to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form (Insert B) indicating the option chosen.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

A. NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer, or failure of a registrant on whom you rely for a generic data exemption either to:

   a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form (Insert A) and a Requirements Status and Registrant's Response Form (Insert B); or,

   b. fulfill the commitment to develop and submit the data as required by this Notice; or,

   c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of

animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

C. EXISTING STOCKS OF SUSPENDED OR CANCELED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or canceled if doing so would be consistent with the purposes of the Federal Insecticide, Fungicide, and Rodenticide Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily canceled products containing an active ingredient(s) for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a

3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Insert A) and a completed Requirements Status and Registrant's Response Form (Insert B) and any other documents required by this Notice, and should be submitted to the contact person identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form (Insert A) need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Bromoxynil DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing bromoxynil.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of bromoxynil. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this DEET Generic Data Call In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for bromoxynil are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on bromoxynil are needed. These data are needed to fully complete the reregistration of all eligible bromoxynil products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Linda Werrell at (703) 308-8033.

All responsades to this Notice for the generic data requirements should be submitted to:

Linda Werrill, Chemical Review Manager
Reregistration Branch
Special Review and Registration Division (H7508W)
Office of Pesticiafde Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Bromoxynil

SPECIFIC INSTRUCTIONS FOR THE GENERIC DATA CALL-IN RESPONSE FORM (INSERT A)

This Form is designed to be used to respond to call-ins for generic and product specific data for the purpose of reregistering pesticides under the Federal Insecticide Fungicide and Rodenticide Act. Fill out this form each time you are responding to a data call-in for which EPA has sent you the form entitled "Requirements Status and Registrant's Response."

Items 1-4 will have been preprinted on the form Items 5 through 7 must be completed by the registrant as appropriate Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U S Environmental Protection Agency, 401 M St , S W , Washington, D C 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D C 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number and address.

Item 2. This item identifies the ease number, ease name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this data call-in but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. Cheek this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. You do not need to complete any item on the Requirements Status and Registrant's Response Form for any product that is voluntarily canceled.

Item 6a. Check this item if this data call-in is for generic data as indicated in Item 3 and if you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and-any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b. Check this Item if the data call-in is a generic data call-in as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this data call-in. Attach the Requirements Status and Registrant's Response Form (Insert A) that indicates how you will satisfy those requirements.

Item 7a. Check this item if this call-in if a data call-in as indicated in Item 3 for a manufacturing use product (MUP), and if your product is a manufacturing use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrants' Response Form (Insert A) that indicates how you will satisfy those requirements.

Item 7b. Check this item if this call-in is a data call-in for an end use product (EUP) as indicated in Item 3 and if your product is an end use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrant's Response Form (Insert A) that indicates how you will satisfy those requirements.

Item 8. This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialed and dated in the space provided for the certification.

Item 9. Enter the date of signature.

Item 10. Enter the name of the person EPA should contact with questions regarding your response.

Item 11. Enter the phone number of your company contact.

SPECIFIC INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANTS RESPONSE FORM (INSERT B)

Generic Data

This form is designed to be used for registrants to respond to call-in- for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of generic data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. DO NOT use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number, and address.

Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the guideline reference numbers of studies required to support the product(s) being reregistered. These guidelines, in addition to requirements specified in the Data Call-In Notice, govern the conduct of the required studies.

Item 5. This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form (Insert B).

Item 6. This item identifies the code associated with the use pattern of the pesticide. A brief description of each code follows:

A.	Terrestrial food
B.	Terrestrial feed
C.	Terrestrial non-food
D.	Aquatic food
E.	Aquatic non-food outdoor
F.	Aquatic non-food industrial
G.	Aquatic non-food residential
H.	Greenhouse food
I.	Greenhouse non-food crop
J.	Forestry
K.	Residential
L.	Indoor food
M.	Indoor non-food
N.	Indoor medical
O.	Indoor residential

Item 7. This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows.

EP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP _ *	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites

TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI	Technical Grade Active Ingredient
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
MET	Metabolites
IMP	Impurities
DEGR	Degradates

***See: guideline comment**

Item 8. This item identifies the time frame allowed for submission of the study or protocol identified in item 2. The time frame runs from the date **of your** receipt of the Data Call-In Notice.

Item 9. Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

1. (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocol and progress reports required in item 5 above.

2. (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-ln Notice.

3. (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am submitting a copy of the form "Certification of Offer to Cost Share in the Development of Data" that describes this offer/agreement. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to making an offer to share in the cost of developing data as outlined in the Data Call-In Notice.

4. (Submitting Existing Data) I am submitting an existing study that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

5. (Upgrading a Study) I am submitting or citing data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

6. (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. I am providing the Agency's classification of the study.

7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching an identification of the basis for this waiver and a detailed justification to support this waiver request. The justification includes, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Item 10. This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. Enter the date of signature.

Item 12. Enter the name of the person EPA should contact with questions regarding your response.

Item 13. Enter the phone number of your company contact.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 5; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your

product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 5).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-99).

This Notice is divided into six sections and six Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form (Insert A)
3 - Requirements Status and Registrant's Response Form (Insert B)
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form (Insert B). Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Insert B, Requirements Status and Registrant's Response Form (Insert B), within the time frames provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form (Insert A), and the Requirements Status and Registrant's Response Form (Insert B). The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form (Insert B) must be submitted for each product listed on the Data Call-In Response Form (Insert A) unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form(Insert A). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form (Insert A) and Requirements Status and Registrant's Response Form (Insert B), initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form (Insert A), indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form (Insert B). If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 5 on the Requirements Status and Registrant's Response Form(Insert A) and item numbers 7a and 7b on the Data Call-In Response Form(Insert B). Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form (Insert B). If you choose one of these options, you

must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form (Insert A) that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form (Insert A) related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form(Insert A). These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced here in and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines(PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form (Insert A) are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does

not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form (Insert A) and a Requirements Status and Registrant's Response Form (Insert B) committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, **all of the following three criteria must be clearly met**:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data

intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-34, Certification with Respect to Citations of Data (in PR Notice 98-5).

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form (Insert A) and the Requirements Status and Registrant's Response Form (Insert B), as appropriate.

III-D. REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice,

pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form(Insert A) and a Requirements Status and Registrant's Response Form(Insert B);

   b. fulfill the commitment to develop and submit the data as required by this Notice; or

   c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or canceled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use

such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily canceled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLEUNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Insert A) and a completed Requirements Status and Registrant's Response Form (Insert B) for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form (Insert A) need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form (Insert A)
3 - Requirements Status and Registrant's Response Form (Insert B)
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

BROMOXYNIL DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing bromoxynil.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of bromoxynil. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this bromoxynil Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for bromoxynil are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on bromoxynil are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible bromoxynil products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Karen Jones at (703) 308-8047.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **BROMOXYNIL**

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORM FOR PRODUCT SPECIFIC DATA

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

Item 7a. For each **manufacturing use product** (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**."

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**." If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

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INSTRUCTIONS FOR COMPLETING THE **REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9. **Enter <u>only one</u> of the following response codes <u>for each data requirement</u> to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed **"Certification with Respect to Citations of Data (in PR Notice 98-5)" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also

submit: (1) a completed **"Certification with Respect to Citations of Data (in PR Notice 98-5)" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed **"Certification of Attempt to Enter into an Agreement with other Restraints for Development of Data " (EPA Form 8570-32)**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

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EPA'S BATCHING OF BROMOXYNIL PPRODUCTS FOR MEETING ACUTE MAMMALIAN TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing Bromoxynil as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwith-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Nineteen active products were found which contain Bromoxynil as the active ingredient. These products have been placed into five batches and a "no batch" group in accordance with the active and inert ingredients, type of formulation and current labeling.

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	264-229	94.0 *	Solid
	264-473	95.0 *	Solid
	33688-8	94.0 *	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
2	264-395	87.3	Solid
	33688-9	87.3	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
3	264-437	33.4	Liquid
	51036-256	33.4	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
4	264-477	Bromoxynil 15.74 Atrazine 21.62	Liquid
	9779-348	Bromoxynil 15.74 Atrazine 21.62	Liquid
	51036-255	Bromoxynil 15.74 Atrazine 21.62	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
5	264-438	Bromoxynil 31.7 Isooctyl ester of 2-methyl-chlorophen-oxyacetic acid 34.0	Liquid
	51036-254	Bromoxynil 31.7 Isooctyl ester of 2-methyl-chlorophen-oxyacetic acid 34.0	Liquid

No Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	264-442	95.0	Solid
	264-531	Bromoxynil [oct] 28.7 Bromoxynil [hep] 27.6	Gel
	264-533	Bromoxynil [oct] 48.8 Bromoxynil [hep] 47.2	Solid
	264-540	Bromoxynil [oct] 28.0 Bromoxynil [hep] 27.0	Liquid
	264-544	Bromoxynil [oct] 18.6 Bromoxynil [hep] 17.9 Isooctyl ester of 2-methyl-chlorophen-oxyacetic acid 39.7	Gel
	264-551	Bromoxynil [oct] 14.6 Bromoxynil [hep] 14.1 Artazine 39.8	Gel
	9779-346	33.4 *	Liquid

(*) Contains the phenolic form of Bromoxynil.

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Pesticide Registration Forms are available at the following EPA internet site:
http://www.epa.gov/opprd001/forms/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk. DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet: at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf.
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf.
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf.
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf.
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf.
8570-32	Certification of Attempt to Enter into an Agreement with other Restraints for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf.
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.

8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
   a 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

   Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.
3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)
   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement
   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
   e. EPA Form No. 8570-35, Data Matrix
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)
   a. Registration Division Personnel Contact List
      Biopesticides and Pollution Prevention Division (BPPD) Contacts
      Antimicrobials Division Organizational Structure/Contact List
   c. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
   d. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
   e. 40 CFR Part 158, Data Requirements for Registration (PDF format)
   f. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information.

These include:

1. The Office of Pesticide Programs' Web Site
2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) the following address:
   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000 and (800) 553- 6847. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.
4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at 1-800-858-7378 or through their Web site.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
the Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.

Documents Associated with this RED

The following documents are part of the Administrative Record for this RED document and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the respective Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.

2. Detailed Label Usage Information System (LUIS) Report.